Premarket Notification (510(k)) Submissions for Bipolar Electrosurgical Vessel Sealers for General Surgery

Guidance for Industry and Food and Drug Administration Staff

Document issued on August 15, 2016.

The draft of this document was issued on March 24, 2014.

For questions regarding this document, contact the General Surgery Devices Branch 2, 301-796-6970.

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Food and Drug Administration
Center for Devices and Radiological Health
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Division of Surgical Devices
General Surgery Devices Branch 2

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Preface

Public Comment

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Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

FDA has developed this guidance document to assist industry in preparing premarket notification (510(k)) submissions for bipolar electrosurgical vessel sealers intended for use in general surgery. These devices are designed to seal isolated blood and lymphatic vessels for hemostasis (as an alternative to ties) through the use of high-frequency electrical current between two electrodes in close proximity.

For the current edition of the FDA-recognized standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database Web site at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Scope

The scope of this guidance document is limited to the Class II electrosurgical devices and accessories classified under the following regulation number:

> **Section 878.4400 Electrosurgical cutting and coagulation device and accessories.**
> An electrosurgical cutting and coagulation device and accessories is a device intended to remove tissue and control bleeding by use of high-frequency electrical current.

This generic type of device includes bipolar vessel sealing instruments, associated electrosurgical generators, and accessories for use in open and minimally invasive general surgical procedures. This guidance is intended only to address bipolar electrosurgical vessel sealers that have general indications for use in general surgery. If your device has specific indications, it may require additional information (e.g., additional bench and/or clinical data) or may be found to have a new intended use. For more information on this topic, please refer to FDA's "Guidance for Industry: General/Specific Intended Use."

This guidance is not intended to address the following devices:

- devices that do not deliver radiofrequency electrical current (e.g., electrocautery, microwave ablation and ultrasonic surgical devices);
- monopolar electrosurgical devices;
- devices that are not indicated for sealing of isolated blood or lymphatic vessels (e.g., devices indicated only for general cutting and coagulation/hemostasis in bulk tissue);
- devices intended for specific surgical procedures or procedures within a given specialty (e.g., ophthalmic use), i.e., anything other than general surgery; and
- reprocessed single-use devices.

In addition, please be aware that this guidance is a supplement to the guidance "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery." This supplemental guidance provides additional recommendations or supersedes the electrosurgical devices guidance. The following sections of the electrosurgical devices guidance are considered applicable to bipolar vessel sealers:

- Software
- Biocompatibility
- Sterility
- Reprocessing
- Pyrogenicity
- Shelf Life
- Electrical Safety and Electromagnetic Compatibility

III. Device Description

We recommend that you identify your device by the applicable regulation number described in Section II and include the following information:

A. Indications for Use

You should provide a clear statement of your device's Indications for Use. The Indications for Use as stated on the Indications for Use Statement page should be identical to that in the 510(k) Summary (if provided in lieu of a 510(k) Statement) and the device labeling. You should also state that the device is a prescription use device, and indicate this accordingly on the Indications for Use Statement page.

Your 510(k) submission should include a comparison of the indications for use of your subject device and all cited predicate devices. The indications for bipolar electrosurgical vessel sealers should clearly state a maximum vessel size measured in the rounded, perfused state in a normotensive subject. If either the subject or predicate devices consist of multiple components with different indications, please specify these differences in your comparison. If you can demonstrate that the intended use of your device in comparison to the predicate is the same, and that there are no new technological characteristics that raise different questions of safety or effectiveness, then you should provide a rationale, including performance data when applicable, for any differences in indications between the subject and predicate device(s).

B. Device Design

You should provide a brief description of the device's operating principle(s) and mechanism of action for achieving the intended effects. If the device will be labeled for use with multiple components or accessories, and the components/accessories are part of the submission, you should provide a list of all components/accessories with accompanying model numbers and/or part numbers. For the purpose of this guidance, components/accessories of vessel sealers refer to the electrosurgical unit (ESU), active components/active accessories, and miscellaneous components/accessories. If there are components/accessories that have received prior 510(k) clearance or are exempted from the 510(k) requirement, please provide the 510(k) numbers or indicate their exemption status, respectively.

At a minimum, you should provide the following information regarding device design:

1. **Device Components**
   We recommend you provide a brief description of all major components or accessories where applicable to your submission:

   - ESU (i.e., the generator and control console) major functions, performance specifications, and physical specifications. If the submission is for a vessel sealing accessory that will be utilized exclusively with a previously cleared generator you may provide the 510(k) number of the generator with a summary of the generators performance specifications (output power, waveform, peak voltage, etc.) in lieu of the major functions, full performance specifications and, physical specifications.
   - Active components/accessories (generally comprised of one or more active electrodes, active connector or cables, and active handle or hand piece) design, physical specifications, and patient contacting materials
   - Miscellaneous accessories such as foot pedal, electrode monitors, etc.

2. **Submission for Specific Component(s)/Accessories**
   If your submission is requesting clearance for a specific component or accessory but not the entire vessel sealer, you should describe the component/accessory. You should discuss how you intend or expect this component/accessory to be used. For example, if the submission is for an active electrode(s) and will only be labeled for use with your own legally marketed devices, you should provide performance testing (see Section V, Performance Data) to demonstrate compatibility with your own

legally marketed devices. Also, you should address the potential that this active electrode could be used with other manufacturers' ESU and identify the associated risk(s). In your risk assessment, please identify whether you have incorporated into your device design a way to prevent using your active electrode with other manufacturers' devices for which compatibility has not been established. Based on your risk assessment, you may need to provide additional performance testing to demonstrate this component will be safe and effective when used with other manufacturers' devices.

3. **Photograph and/or Drawing of the Device**
   We recommend you provide high-level drawings, diagrams, and/or photographs of the device that can help explain the functions and features. We also recommend you provide an exploded or assembly view diagram or connection diagram, including all components clearly labeled.

IV. Substantial Equivalence Comparison

We recommend that you compare your device with a legally marketed predicate device(s) that you believe is (are) substantially equivalent to your device with respect to indications for use and technology characteristics per 21 CFR 807.87(f). Side-by-side comparisons for each major component using a tabular format such as shown in Table 1 are desirable whenever possible. For each identified difference, please provide further discussion of the difference compared to the predicate and why this difference will not significantly affect safety or effectiveness. You may need to provide performance data to support that, even with significant differences, the device is as safe and effective as the predicate.

Table 1. Example Comparison Table

Description	Your Device	Predicate Device
Indications for Use		
ESU • Major functions (e.g., monopolar and/or bipolar, temperature or impedance feedback system, electrodes monitoring, automatic detection of complete seal, method of activation, alarm functions). [*Please note: Power generators for vessel sealers should be bipolar; however, if the generator has additional monopolar functions for cutting or coagulation, these functions should be described accordingly.*] • Performance specifications (e.g., output frequency, waveform, power output, voltage output, crest factor) • Physical specifications		
Active Components/Accessories • Physical dimensions and design (e.g., size, length, connector type) • Tip design/shape • Mechanism of cutting (e.g., mechanical and/or electrical) • Rated voltage • Materials (electrode, insulation, coating, etc.)		
Miscellaneous Accessories • Functions • Performance specifications • Physical specifications • Materials		
Vessels • Type • Maximum diameter • Size range		

When more than one predicate device is identified to establish substantial equivalence of your device, you should provide justification for the use of each predicate. You should address why the combination of features and/or functions into one device does not raise different types of safety and effectiveness questions for each predicate identified. An example of where multiple predicates could be used is if the device includes different technologies that can stand alone but

can also be used together for the intended use of sealing vessels. If there is a predicate device for each of the technologies, then the combination of these technologies, assuming that the use of one of the functions does not interfere with the others, could be found substantially equivalent. In such an instance, you may need to provide performance data to support your justification.

V. Performance Data

We recommend that nonclinical testing be performed to demonstrate that each individual component of the vessel sealing system (or a representative from each family of closely related components) as well as the overall vessel sealing system with all the components connected (system) meets all the design and performance specifications. In the case where the 510(k) submission is for one or more components of the vessel sealing device, but not the entire vessel sealer (e.g., ESU only or active electrodes only), nonclinical testing as a system should be provided using legally marketed components with which your device is labeled as compatible. In the case where the 510(k) submission is for a vessel sealer and other active components of an electrosurgical device, recommendations for the necessary performance data for other active components/accessories of the electrosurgical device may apply. Please refer to the FDA guidance "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery."

Depending on the substantial equivalence comparison to the predicate(s) above, nonclinical testing may be accomplished with bench testing alone, or it may necessitate testing in an *in vivo* or *ex vivo* animal model. The following are recommended nonclinical tests for each major component and for the system.

You should provide full test reports for each test conducted. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, and conclusions. You should also provide an explanation of how the data generated from the test supports a finding of substantial equivalence. For any tests involving tissue effects, you should describe the clinical relevance of the acceptance criteria for each test and explain why the test results demonstrate acceptable clinical performance of your device. Nonclinical test conditions should simulate the worst-case conditions that your device is likely to encounter during clinical use. For those nonclinical tests that do not rely on FDA recognized consensus standards, the results of the testing on the proposed device should be compared to those of your predicate device(s).

A. ESU

You should provide a graphical display of the output waveform at the rated load, identifying the associated mode, amplitude, frequency, duty cycle, load used, and crest factor.

You should provide a graph displaying the power output at maximum and half-of-maximum intensity over the range of expected loads (e.g., 50 Ω to 500 Ω for bipolar). This information should be derived from experimental test data and not theoretical values, and it should include a comparison of these curves to the corresponding mode of the predicate device(s).

If the vessel sealer ESU possesses additional functions such that it can also perform as a high frequency surgical generator for other procedures besides vessel sealing, you should provide information for each mode of the ESU. Please refer to FDA's guidance, "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery."

B. Active Components/Accessories

Mechanical testing of the active electrodes and instruments of the vessel sealer is important to minimize the risks associated with mechanical failure and short circuiting. Although the methods will vary based on the device design, you should assess the potential for damage to the device both before use (e.g., drop tests of the instrument in its packaging) and during use (e.g., bending force). Different considerations will also be necessary for single-use instruments versus reusable instruments. For reusable instruments, testing should demonstrate both adequate mechanical strength and electrical performance (e.g., insulation integrity) after multiple reuse and reprocessing cycles. For instruments with actuating parts, we recommend simulated repeated-use testing of the actuating part, including grasping force and force to jaw failure. Force to jaw failure is defined as the force required to cause the actuating component to no longer be able to grasp or close on the target tissue. This testing is important to ensure that the device can appropriately grasp the target tissue under worst case scenarios. For reusable instruments, this testing should be conducted after the maximum number of simulated use and reprocessing cycles.

C. Miscellaneous Components/Accessories

When your vessel sealing device also includes accessories such as a foot pedal, you should provide test results to show that each miscellaneous device meets all of the design specification and performance requirements.

If a component/accessory has been previously cleared by FDA, you may provide the original 510(k) as a reference, rather than conducting additional tests for the referenced component/accessory. However, compatibility between the component/accessory and the proposed device should still be addressed.

D. System Testing

We recommend the following system testing to demonstrate bipolar electrosurgical vessel sealer performance when the 510(k) is for a new vessel sealing system or modifications that can reasonably be expected to modify the tissue effect of the system (i.e., change in jaw geometry or materials, jaw surface characteristics, clamping force, output power, or the generator control algorithm). Where the 510(k) includes a family of closely related devices that share the same jaw geometry or materials, jaw surface characteristics, clamping force, output power, and generator control algorithm, it is not necessary to repeat the system testing for all members of the family. The justification for relying on a family representative, or otherwise pooling data, should be provided in the protocol and/or report. This information should include testing on both the subject device and the predicate device(s) for comparison.

1. **Burst Pressure**
   For each mode and representative instrument, you should provide burst pressure testing data to evaluate the seal strength of vessels sealed with your device when compared to vessels sealed with the predicate device. In this testing, vessels are sealed with the subject device and the predicate device. These vessels are then pressurized with liquid until failure. The maximum recorded pressure immediately prior to failure is recorded as the burst pressure.

   You should select a range of vessel sizes consistent with your indications for use and provide a rationale for the specific vessel types (veins, arteries, or both) selected. You should provide a thorough test report that includes a table listing each vessel sealed with information on burst pressure, vessel type, diameter, device sample number, physical observations (e.g., sticking, charring), and any errors or notes (e.g., the first seal attempt gave an alarm and the device was reapplied). You should use the data from the burst pressure testing to determine the worst-case scenario for your chronic animal study by focusing on vessel sizes that present the most difficulty sealing or exhibit failures during the burst pressure testing.

2. **Thermal Spread on Vessels**
   For each mode and representative instrument, you should provide comparative data to evaluate the spread of thermal damage along the vessels. These data should include a quantitative measurement (under magnification) of the size (length, width, and depth) of the thermal damage zone. Two-dimensional histological assessments (e.g., length and width) are considered to be minimally acceptable measurements for assessing thermal spread. Three-dimensional histological assessments (e.g., length, width, and depth) should be performed as necessary to quantify thermal spread in seals that generate special growth characteristics (e.g., asymmetrical growth of the thermal spread).

   In this testing, vessels are sealed with either the subject or predicate device and the thermal damage (i.e., coagulation necrosis) is then assessed histologically to determine the distance from the edge of the seal.

   We recommend that you seal the vessels *in vivo* or provide a rationale for why *ex vivo* use does not impact the results. You should provide a thorough test report that includes representative high-quality, color images of several histology samples from each group that clearly indicate the edge of the seal and how the measurements were made.

E. Chronic Animal Study

We recommend chronic animal studies to demonstrate bipolar vessel sealing performance when the 510(k) is for a new vessel sealing system or modifications that can reasonably be expected to modify the tissue effect of the system (i.e., change in jaw geometry or materials, jaw surface characteristics, clamping force, power, or the generator control algorithm).

Where the 510(k) submission includes a family of closely related devices that share the same jaw geometry or materials, jaw surface characteristics, clamping force, power, or the generator control algorithm, it is not necessary to repeat the system testing for all

members of the family. The justification for relying on a family representative, or otherwise pooling data, should be provided in the protocol and/or report.

In order to assess the long-term seal quality and potential for injury to adjacent structures, you should perform a chronic animal study to evaluate your device performance at a minimum of 3 weeks post-procedure in at least 5 animals. Multiple vessels per animal should be sealed for an adequate study sample size. This study may be done with only the proposed device, provided success criteria are pre-defined and clinically justified (e.g., no vessel leaks, normal vessel healing, and no adjacent tissue damage) and similarly produced data from the predicate device are available for comparison. You should provide a thorough test report that includes the following information at a minimum:

- justification of the animal model and vessels chosen with respect to vessel type (e.g., artery and vein) and diameter;
- a description of the surgical procedure, including if and how the vessels were transected after sealing and how the seals will be located at necropsy;
- a description of the intra-operative evaluation of vessel leakage prior to closing the animal;
- if intensity (i.e., power setting) is adjustable, a rationale for the output intensities used (in this case, we recommend testing a range of values that includes the worst-case setting);
- a table that lists each vessel sealed with information on vessel type, diameter, device sample/identification number, seal appearance, gross findings at necropsy (e.g., unforeseen injury, large hematoma over the sealed site, adjacent tissue damage), and any comments related to failure or success of the sealing;
- an animal husbandry/veterinary clinical observations report of how the animals fared from the time of operation to necropsy, with explanations of any clinical symptoms;
- the post-surgical activity level of the animals, which should not be restricted, and a description of any stress placed on the animals (i.e., to elevate blood pressure); and
- a histopathology report that describes the extent of vessel healing, evidence of leakage (hemorrhage and/or edema), and any adjacent tissue damage.

Acceptable methods of identifying how seals are to be located at necropsy should be documented in the original protocol and the final test report. Accordingly, the protocol and report should confirm the anatomical location(s) where the seals are performed. Sutures and ink are acceptable means for marking the specific seals within the anatomical areas documented in the protocol and report.

Since the nonclinical animal studies recommended above will be used to help establish the safety of the device, they must be conducted according to Good Laboratory Practices (GLPs) established by 21 CFR part 58.

VI. Clinical Testing

Clinical data are generally not necessary to support 510(k) submissions for bipolar electrosurgical vessel sealers intended for use in general surgery. However, if your device indications for use or device technology and/or mechanism of action is significantly different when compared to the predicate device(s), and if nonclinical testing is insufficient to establish substantial equivalence, clinical testing may be necessary to establish substantial equivalence to a predicate device.

If you believe that clinical data are necessary, or if you are uncertain, we highly recommend that you contact the Agency through the Pre-Submission process to obtain early feedback on study design considerations (see the FDA guidance, "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff").

VII. Labeling

The premarket notification must include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). Proposed labels, labeling, and advertisements sufficient to describe the vessel sealing device, its intended use, and the directions for use must be provided with a specific intended use statement and any warnings, contraindications, or limitations clearly displayed as described in 21 CFR 807.87(e). Please consider the following suggestions for assistance in preparing labeling that satisfies the requirements of 21 CFR 807.87(e). The following suggestions are aimed at assisting you in preparing acceptable labeling.

Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR part 801 before a medical device is introduced into interstate commerce. In addition, final labeling for prescription medical devices must comply with 21 CFR 801.109.

As a prescription device, under 21 CFR 801.109, the device is exempt from having adequate directions for lay use. Labeling must, however, include adequate information for practitioner use of the device, including indications, effects, routes, methods, frequency and duration of administration and any relevant hazards, contraindications, side effects, and precautions (21 CFR 801.109(d)).

We recommend that all bipolar electrosurgical vessel sealer submissions demonstrate compliance with the labeling sections of the currently FDA-recognized versions of the 60601 series of standards, including AAMI/ANSI ES60601-1, IEC 60601-1-2, IEC 60601-2-2, and (when applicable) IEC 60601-2-18. We also recommend that you include the information below in your labeling. Please note that some of the recommended labeling content is already included in the standards but has been repeated for emphasis. Other recommended content has been modified from the standards.

Vessel sealing systems generally consist of several different interchangeable components used together to create the desired effect, including the ESU, reusable instruments, disposable instruments, footswitches, etc. Some of the labeling recommendations below may apply to only a single component or to each component in a system. You should determine which labeling is

appropriate, depending on the indications for use, the individual components, and how the components may be packaged (together or separately).

The list below is not intended to be exhaustive of all the labeling requirements under part 801.

A. Instructions for Use (User Manual)

1. **Indications for Use**
   Your labeling should clearly state the indications for use of your device as specified in your Indications for Use Statement. This information should be prominently located in the beginning of your directions for use. If your device consists of multiple components with different indications, please specify this in your labeling.

2. **Contraindications**
   We recommend including the following contraindication for bipolar vessel sealers:

   This device has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use this device for these procedures.

3. **Warnings**
   We recommend including the following warnings, as applicable, in the instructions for use. Sample language is provided in italics. If you believe any of these warnings are not applicable to your device, please provide a justification for each omission.

   a. *DO NOT USE in patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (e.g., cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged.*

   b. *DO NOT USE this instrument on vessels larger than __mm in diameter.*

   c. *DO NOT USE in the presence of flammable anesthetics or oxidizing gases (such as nitrous oxide (N_2O) and oxygen) or in close proximity to volatile solvents (such as methanol or alcohol), as explosion may occur.*

   d. *DO NOT place instruments near or in contact with flammable materials (such as gauze or surgical drapes). Instruments that are activated or hot from use may cause a fire.*

   e. *When not using instruments, place them in a clean, dry, highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.*

   f. *DO NOT place the vessel and/or tissue in the jaw hinge. Place the vessel and/or tissue in the center of the jaws.*

   g. *PRIOR TO CUTTING, inspect the vessel or tissue to ensure proper sealing.* (If the device uses a simultaneous seal-and-cut technology, this warning can be omitted.)

   h. *DO NOT USE energy based devices to transect seals, such as electrosurgical pencils or ultrasonic scalpels.*

i. *DO NOT attempt to seal over clips or staples or contact metal objects (e.g., retractors). Contact between an active electrode and any metal objects may result in alternate site burns or incomplete seals.*

j. *INSPECT reusable instruments and cables for damage prior to each use, especially the insulation of laparoscopic/endoscopic instruments. This may be done visually under magnification or with a high voltage insulation testing device. Insulation failures may result in burns or other injuries to the patient or operator.*

k. *ASPIRATE fluid from the area before activating the instrument. Conductive fluids (e.g., blood or saline) in direct contact with or in close proximity to an active electrode may carry electrical current or heat away from target tissues, which may cause unintended burns to the patient.*

l. *The surface of the active electrode may remain hot enough to cause burns after the RF current is deactivated.*

m. *Due to concerns about the carcinogenic and infectious potential of electrosurgical byproducts (such as tissue smoke plume and aerosols), protective eyewear, filtration masks, and effective smoke evacuation equipment should be used in both open and laparoscopic procedures.*

n. *Connect adaptors and accessories to the electrosurgical unit only when the energy is off. Failure to do so may result in an injury or electrical shock to the patient or operating room personnel.*

4. Cautions

We recommend including the following cautions, as applicable, in the instructions for use. Sample language is provided in italics. If you believe any of these cautions are not applicable to your device, please provide a justification for each omission.

a. *The intensity should be set as low as is necessary to achieve the desired effect.*

b. *Do not overfill the jaws of the instrument with tissue, as this may reduce device performance.*

c. *Keep the active electrodes clean. Build-up of eschar may reduce the instrument's effectiveness. Do not activate the instrument while cleaning. Injury to operating room personnel may result.*

d. *Use caution during surgical procedures in which patients exhibit certain types of vascular pathology (atherosclerosis, aneurysmal vessels, etc.). When possible, apply the seal to unaffected vasculature.*

5. Summary of Animal Studies

You should provide a summary of the data from your animal studies to demonstrate that your device worked in this animal model to achieve sealing in arteries and veins of the tested size. You should also include a statement to the effect that clearance was not based on human clinical testing, and that there is no animal model predictive of how the device functions when used to seal vessels containing atherosclerotic plaque.

6. **Operating Information**
   Operating instructions should contain detailed information such that the practitioner can set up and use the device safely and for the purposes for which it is intended. In addition, we recommend that you include instructions concerning the proper selection and use of accessories in order to avoid incompatibility and unsafe operation. For any accessories that may need to be replaced (e.g., disposable electrodes), you should also provide instructions in your labeling for obtaining replacements (e.g., model number and contact information).

B. Device Labels

In your submission, we recommend that you provide illustrations to show how each component/accessory of your device is labeled to demonstrate that all controls, switches, and connections (including those for hand switched active electrodes and foot switches) are clearly, concisely, and permanently labeled to identify their function and other important information (e.g., Type BF Applied Part). In the submission and the labeling, you should also describe the color of any controls or connections (e.g., blue "coag" button) so that the function of each is apparent.

C. Package Labels

We recommend that you provide draft package labels, which should include the manufacturer, model number, and important information about device reuse, sterility, shelf life, etc.

D. Labeling for Specific Components

1. **ESU**
   Your directions for use should include information on the output specifications of your device so that the user can easily understand the energy that is being delivered. We recommend including the following information for each output mode of your device:

   a. Graphs or tables illustrating the actual power output (under a specified impedance). These graphs or tables should be provided for each intensity setting if multiple intensity settings are available.

   b. Graphs displaying the power output at maximum and half-of-maximum intensity over the range of expected impedances.

   c. The maximum output voltage and instructions regarding selecting accessories with appropriate voltage ratings.

2. **Active components and active accessories**
   Your directions for use should include information on the compatibility of your instrument with other components of the electrosurgical system. We recommend including the following information:

   a. The rated accessory voltage.

   b. The compatible generator model or adequate instructions and criteria for the user to identify an adequate generator.

c. The limitations on generator output settings and duration of activation.

d. A statement referring users to the generator manual for additional instructions.

e. If the instrument is reusable, adequate instructions on the cleaning, inspection, and sterilization and how to track the number of uses. You should also include a warning that visual inspection alone may not be sufficient to ensure that the insulation is intact.

3. Components and Accessories

Your directions for use should include information on the compatibility for each of your accessories with the vessel sealing device. For some accessories, such as suction/irrigation pumps and smoke evacuation devices, a separate standalone instructions for use should be considered.

Appendix A: Glossary of Terms

The following terms are defined for the purpose of this guidance only and may or may not correspond to their broader usage.

Active accessory – The component of the electrosurgical device used by the operator to produce surgical effects at the intended site on the patient. Generally comprised of an active handle, the cord or cable, and the active electrode (may be monopolar or bipolar for general electrosurgical units).

Active electrode – The conductive portion of the electrosurgical instrument that delivers high density electrical current to the patient at the surgical site. This may or may not be removable from the instrument handle.

Bipolar – An electrosurgical device in which the current flows between two active electrodes placed in close proximity.

Coagulation – The change of a liquid, especially blood, to a solid. This is considered separate from coagulation necrosis.

Coagulation necrosis – Necrosis in which the affected cells or tissue are converted into a dry, opaque, fairly homogenous eosinophilic mass as a result of the coagulation of protein.

Continuity monitor – A component of a monopolar electrosurgical system that monitors the connection between the neutral electrode and the generator. The continuity monitor produces an alarm if the connection is lost, but it cannot detect if there may be a high current density through the neutral electrode.

Electrocautery – The use of electric current to heat an instrument, which is applied to tissue to create an effect. The current passes through the instrument only and not through the patient's tissue.

NOTE: The term electrocautery is often used incorrectly to refer to electrosurgical devices. To prevent confusion, FDA recommends that you avoid misuse of this term.

Electrosurgical device – A device that passes high-frequency electrical current through soft tissues for the purpose of removing tissue or controlling bleeding.

ESU – Abbreviation for electrosurgical unit. This term refers to the generator and control console.

Generator – The component of the electrosurgical system that produces the high-frequency current waveform that is delivered to tissues via the connecting cable(s), instrument(s), and electrode(s).

Instrument – The component of the electrosurgical system that is manipulated by the operator and applied to the surgical site, generally consisting of the handle and active electrode.

Radiofrequency (RF) – Generally refers to frequencies ranging from 100 kHz to 5 MHz. This is intended to exclude other frequencies (e.g., microwave ablation devices) that may technically fall within the radiofrequency portion of the electromagnetic spectrum but operate in a fundamentally different manner.

Vessel sealer – An electrosurgical device intended to seal isolated blood and lymphatic vessels for hemostasis, as an alternative to ties. Usually bipolar.

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