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Product Labeling for Certain Ultrasonic Surgical Aspirator Devices

Guidance for Industry and Food and Drug Administration Staff

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For questions about this document, contact the Obstetrics-Gynecology Devices Branch, 301-796-7030 for gynecologic indications, or the General Surgery Devices Branch 2, 301-796-6970 for general surgical indications.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

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Preface

Public Comment

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I. Introduction

The Food and Drug Administration (FDA) is issuing this guidance to recommend the addition of a specific safety statement to the product labeling of certain ultrasonic surgical aspirator devices. Ultrasonic surgical aspirator devices are surgical tools intended to fragment, emulsify and aspirate hard and soft tissue. These devices can be used in many different surgical specialties for a wide range of procedures, including the debulking of malignant tumors. Ultrasonic surgical aspirators cause tissue fragmentation through the delivery of ultrasound energy to target tissue through an oscillating tip. Tissue fragments are aspirated through the inner lumen of the device. This mechanism of action creates the potential for tissue dissemination. The incorporation of suction/aspiration reduces but cannot eliminate this potential.

In light of the risk of tissue dissemination from use of these devices, the FDA is providing a specific labeling recommendation in this guidance to promote the safe and effective use of ultrasonic surgical aspirator devices.

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 guidance means that something is suggested or recommended, but not required.

II. Background

Ultrasonic surgical aspirator devices may be indicated for use in a wide range of surgical applications, including but not limited to neurosurgery, plastic and reconstructive surgery, orthopedic surgery, laparoscopic surgery, open surgery, and gynecologic surgery. Because ultrasonic surgical aspirator devices use an oscillating tip to cause tissue fragmentation through

the delivery of ultrasound energy to target tissue, there is the potential for tissue dissemination that is mitigated but not completely eliminated by the use of suction/aspiration.

FDA is aware that ultrasonic surgical aspirator devices are sometimes used to treat advanced malignancy through cytoreduction (also known as debulking). In these cases, the device is used to remove a portion of a malignant tumor that cannot be completely excised, in an effort to enhance the effectiveness of ancillary treatments (such as radiation or chemotherapy). When used in advanced cancers, the risk of adverse clinical effects from tissue dissemination may be small compared to the device's potential benefits, such as more extensive tumor debulking, no/minimal collateral thermal damage, and the ability to avoid resection/removal of organs.

However, in certain clinical circumstances, the unintended dissemination of cancerous cells may have a significant adverse effect that outweighs any demonstrated benefits. FDA is aware that labeling of certain ultrasonic surgical aspirator devices allows for use in the removal of uterine fibroids, although this use may not be explicitly stated in the labeling and FDA is not aware of these devices being used for this purpose.[1] There are currently no reliable preoperative screening procedures to detect uterine sarcoma in women with presumed benign fibroids. Use of an ultrasonic surgical aspirator during treatment for symptomatic uterine fibroids on a woman with an occult uterine sarcoma could result in dissemination of this cancer. This risk of cancer dissemination outweighs any potential benefits in this patient population, particularly since there are alternative treatment options available.

For these reasons, FDA recommends that the labeling of certain ultrasonic surgical aspirator devices include a contraindication against use of the devices for removal of uterine fibroids.

III. Scope

Ultrasonic surgical aspirator devices may have general indications for use (e.g., laparoscopic surgery, open surgery) or specific indications for use (e.g., gynecologic surgery). This guidance, and the labeling recommendation below, applies to ultrasonic surgical aspirator devices with indications for use in laparoscopic surgery, open surgery, or gynecologic surgery as such surgeries can include gynecologic procedures. These devices are regulated under several different product codes, including LFL (Instrument, Ultrasonic Surgical) and NLQ (Scalpel, Ultrasonic, Reprocessed). Some devices regulated under these product codes may utilize different technology (e.g., they do not aspirate), and would not fall within the scope of this guidance.

[1] On November 25, 2014, FDA issued the "Immediately in Effect Guidance Document: Product Labeling for Laparoscopic Power Morcellators" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM424123.pdf) to address new scientific information that represents a significant change to the benefit/risk profile for laparoscopic power morcellators (LPM). Specifically, FDA reviewed scientific information that suggests that the use of LPMs contributes to the dissemination and upstaging of an occult uterine malignancy in women undergoing laparoscopic gynecologic surgery for presumed fibroids. FDA is generally not aware of reports of dissemination or upstaging of occult uterine malignancies related to ultrasonic surgical aspirators at this time. FDA is recommending the contraindication in this guidance, rather than the contraindication in the LPM guidance, in light of the fact that ultrasonic surgical aspirators are generally not intended nor used for the removal of uterine fibroids.

This guidance does not apply to ultrasonic surgical aspirator devices with an indication for use only for other surgical subspecialties, e.g., gastrointestinal and affiliated organ surgery, urological surgery, neurosurgery. For example, this guidance would not apply to devices indicated only for neurosurgical fragmentation and aspiration.

IV. Recommended Labeling Statement

FDA recommends that manufacturers of ultrasonic surgical aspirator devices with indications for use in laparoscopic surgery, open surgery, or gynecologic surgery prominently include the following Contraindication in their product labeling:

> ***CONTRAINDICATION: This ultrasonic surgical aspirator device is not indicated for and should not be used for the fragmentation, emulsification, and aspiration of uterine fibroids.***

In addition to including the above Contraindication in the product labeling, we recommend manufacturers review and update other portions of their labeling to be consistent with this Contraindication. For example, a manufacturer may revise the list of procedures in the labeling for which the ultrasonic surgical aspirator can be utilized.

FDA believes accurate product labeling is important to make health care providers and patients aware of situations when these devices should not be used. FDA believes that the Contraindication is important for the safe and effective use of these ultrasonic surgical aspirator devices.

Within 120 days of the publication of this guidance, a manufacturer with an existing 510(k) clearance should: 1) add the Contraindication to its labeling; 2) submit both the current labeling and revised labeling to the Center for Devices and Radiological Health (CDRH); and 3) provide updated labeling to purchasers of these ultrasonic surgical aspirator devices that have already been distributed.[2]

If a manufacturer with an existing 510(k) clearance adds the Contraindication listed above, FDA does not intend to object if such labeling changes are submitted as an amendment ("add to file") to the existing 510(k) rather than as a new 510(k). We recommend that manufacturers bundle 510(k) amendments for these labeling changes as appropriate.

In addition, manufacturers submitting a new 510(k) for a new or significantly modified device should include these labeling recommendations in the submission.

[2] FDA recommends that a manufacturer provide updated labeling in a way to help ensure purchasers are aware of it, such as posting the updated labeling on the manufacturer's website and notifying purchasers that they can access the updated labeling on that website.