Guidance for Industry and FDA Reviewers/Staff

Guidance Document for Powered Suction Pump 510(k)s

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

General Surgical Devices Branch
Division of General and Restorative Devices
Office of Device Evaluation

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Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to General Surgical Devices Branch, HFZ-410, 9200 Corporate Boulevard, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Mr. Berry F. Williams, MS at (301) 594-1307, ext. 137 or by electronic mail at (bfw@cdrh.fda.gov).

Additional Copies

World Wide Web/CDRHhome page: http://www.fda.gov/cdrh/ode/powerpump.pdf or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 2207 when prompted for the document shelf number.

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Guidance[1] Document for Powered Suction Pump 510(k)s

INTRODUCTION -

This document outlines specific information to be submitted for a powered suction pump premarket notification (510(k)). A 510(k) should provide information to support substantial equivalence of the proposed device to a device legally in commercial distribution. Substantial equivalence is to be established with respect to, but not limited to, intended use, design, energy used/delivered, materials, performance, safety, effectiveness, labeling, and other applicable characteristics.

PURPOSE -

This guidance is intended to:

1. assist manufacturers, distributors, or importers in organizing premarket notifications for powered suction pumps and accessories;

2. achieve consistency in meeting requirements and in the presentation of information; and

3. guide FDA staff in conducting and documenting the review of powered suction pump premarket notifications.

OVERVIEW -

Powered Suction Pumps are described in the FDA regulations, 21 CFR 878.4780. A powered suction pump is a portable, AC-powered , or compressed air-powered device intended to be used to remove infectious materials from wounds or fluids from a patient's airway or respiratory support system. The device may be used during surgery in the operating room or at the patient's bedside. The device may include a microbial filter. The FDA classified the device as a class II device. We encourage manufacturers to identify the applicable sections of the standard(s) which was used in testing the powered suction pumps (e.g., ANSI/AAMI American National Standard for Electrosurgical Devices HF-18/1993 and /or International Electrotechnical Commission Standard for Electrosurgical Devices, 601-2-2).

POWERED SUCTION PUMPS TERMINOLOGY AND DEFINITIONS -

Code of Federal Regulations: 21 CFR 878.4780
JCX - Apparatus, Suction, Ward Use, Portable AC-Powered
BTA - Pump, Portable, Aspiration, (Manual or Powered)
DSMA - Division of Small Manufacturer's Assistance

[1] This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

SUGGESTED FORMAT -

- **General information** -
  a. Trade name including the model number of the device.
  b. Common name or the classification name (21 CFR 807.87) of the device.
  c. Establishment registration number.
  d. Address of manufacturing facility/facilities.
  e. The classification in which the device has been placed (Class I, II, III, or not classified) under section 513 of the act, and, its appropriate panel, if known. If the submitter determines that the device has not been classified, a statement of that determination and the basis for that determination.
  f. The reason for the premarket notification - a new device or a modification to an existing device. If the 510(k) is for a modification, describe in detail the reason for the modification and provide the 510(k) number for the original device.
  g. Identification of a legally marketed predicate device to which you claim equivalence.
  h. Compliance with standards or guidelines.

- **510(k) Summary and/or certification statement in accordance with Safe Medical Device Act of 1990** - see 57 FR 18066, April 28, 1992 as amended in 59 FR 64295 on December 14, 1994.

- **Proposed Labeling** - see ODE Bluebook Memo G91-1, Device Labeling Guidance. A copy of this guidance may be obtained from DSMA.
  a. Intended use.
  b. Prescription labeling in accordance with 21 CFR 801.109 (b)(1).
  c. Identification labels.
  d. Provide all labeling including adequate directions for use, advertisements, appropriate directions for re-processing/disinfection/sterilization, maintenance, etc. Include all cautions, warnings, precautions, contraindications or limitations.
  e. Sterilization instructions. The repeated re-sterilization should not compromise the performance of the device.
  f. Provide the intervals for routine maintenance.
  g. Detailed instructions in addition to sterilization including the following:
     * Assembly/disassembly
     * Detailed cleaning

- **Detailed Device Description** - Please provide the following:
  a. Performance Specifications
     (1) Type of pump (e.g., AC, DC, Microprocessor Controlled, etc.)
     (2) Maximum suction flow rate
     (3) Pressure controls
     (4) Filter (e.g., bacterial filter having a pore size range of 0.3 microns)
     (5) Power operations (i.e., VAC, Hz, etc.)
     (6) Safety Features (e.g. electronic and manual):
        - sensor - an electronic system that monitors the pressure created by the unit and pressure generated in the suction bottle. If the pressure in the bottle and unit becomes unequal, the suction automatically stops. This prevents the back-up of fluid into the pump and patient.
        - overflow valve - a manual safety feature positioned into the cap of the suction bottle. If fluid reaches a maximum level in the bottle, floats in the overflow valve will block the inlet port, causing suctioning to automatically stop. This prevents back-up of fluid to either the pump or the patient.

     (7) Accessories:
        - collection bottles/canisters - size, type, etc.
        - tubing - material, specifications

  b. Detailed schematic, assembly, and engineering drawings.
     (1) Vacuum pump
     (2) Features (e.g., start/stop switch, preadjustment of suction pressure, hardware, read outs for set points, actual pressure, etc.)
     (3) Software (if applicable)
     (4) Collection system

- **Comparative Information** - The following should be provided in side by side tabular form:
  a. Identify predicate device(s) with the same intended use for comparison.
  b. Provide side by side comparisons including similarities and differences.
     (1) Comparisons in physical description, performance specifications, materials, dimensions, and other characteristics.
     (2) Comparisons in testing and operating parameters.
  c. Explain the consequences and effects of changes or modifications and how the differences affect the use and safety of the device.

- **Biocompatibility** - Typically powered suction pumps do not contact patients, so biocompatibility is not an issue. If there is a patient contacting part of a pump (i. e, suction tip), please see our Bluebook Memo G95-1, entitled "Use of International Standard ISO 10993, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing" for guidance on Biocompatibility.

- **Sterilization Information**

  a. Sterile devices - Typically suction pumps have no components provided sterile. If your device does include sterile components (e.g., suction tip, tubing, suction bottles, suction bottle caps, etc.) please provide the following:
  (1) Method of sterilization used (ETO, RAD, Steam).
  (2) Sterility Assurance Level (SAL) attained.

  b. Reusable sterile devices - Please follow the *Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance*.

- **Software Validation** - Typically powered suction pumps do not include software. If your device does include software, please see the Guidance for the Content of Premarket Submissions for software contained in Medical Devices (5-29-98). A copy of this guidance may be obtained from DSMA.

References are available at our web site:

http://www.cdrh.fda.gov/cdrh/topindx.html-G for guidances.
http://www.cdrh.fda.gov/cdrh/blbkmem.html for Bluebook Memos.