

K033425

Special 510(k) - ambIT™ Intermittent Infusion Pump

NOV - 6 2003

510(k) Summary

Submitted by:

Douglas Bueschel
Director Regulatory Affairs and Quality Assurance
Sorenson Medical, Inc.
1375 West 8040 South
West Jordan, Utah 84088-1888

Name/Classification of the Device:

Infusion Pump/Class II, 80FRN – 21 CFR 880.5725

Trade Names:

ambIT™ Intermittent Ambulatory Infusion Pump, or
ambIT™ Pump

Predicate Device:

Palm Pump, #K002434 cleared on August 23, 2000. This predicate device is manufactured by Sorenson Medical, Inc.

Statement of Intended Use:

The ambIT™ Intermittent Ambulatory Infusion Pump is intended for the Intermittent volumetric delivery of intravenous medicines and/or fluids into patients at a preset rates and volumes for prescriptive treatment by a physician.

Device Description:

Sorenson Medical's ambIT™ Intermittent Ambulatory Infusion Pump is compact, lightweight, microcomputer-controlled pumps that use rotary peristaltic pumping technology. The modified device differs only slightly from the Palm Pumps (K002434) already marketed. Changes have been made to that pump to incorporate three roller gears instead of two, a modified PCB, a change to color and name, and a software revision to provide for intermittent fluid delivery to specified output requirements.

Summary of Technological Characteristics of New Device to Predicate Device:

The technological features of the ambIT™ Intermittent Ambulatory Infusion Pump are identical to the predicate Palm Pump except for the deletion of several software capabilities required for intermittent pumping action, a modified PCB and the addition of one additional roller gear in the disposable sterile infusion cassette. Case color has also changed from a blue to a cool grey. The subject and predicate devices are similar in design, labeling and manufacturing and share the identical materials and components. The subject and predicate devices are the same in intended use. The technological differences between the subject and predicate devices are minor and they do not raise issues of safety and effectiveness.

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Discussion of Non-Clinical Tests; Conclusions Drawn from Non-Clinical Tests:

The requirements and results of documented verification and validation testing were defined and were conducted according to Sorenson Medical quality system requirements to verify that the design modifications made to the subject device met documented performance and safety requirements specified for the new device. All tests were conducted according to written test protocol, with defined test expectations and documented conclusions. All test data has been attached to the verification and validation testing performed and is a permanent record of Sorenson Medical's Design History Record.

Labels and Labeling:

Labels and labeling, including the User's Manual are similar to the predicate Palm Pump and meet all FDA and E.U. requirements for a medical device product.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sorenson Medical Incorporated
Mr. Douglas Bueschel
Director Regulatory Affairs and Quality Assurance
1375 West 8040 South
West Jordan, Utah 84088-8320

Re: K033425

Trade/Device Name: AmbIT™ Intermittent Ambulatory Infusion Pump
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: October 15, 2003
Received: October 27, 2003

Dear Mr. Bueschel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Special 510(k) - ambIT™ Intermittent Infusion Pump

510(k) Number (if known): K033425

Device Name: ambIT™ Intermittent Ambulatory Infusion Pump

Indications for Use:

The ambIT™ Intermittent Ambulatory Infusion Pump is intended for the Intermittent volumetric delivery of intravenous medicines and/or fluids into patients at predetermined rates and volumes for prescriptive treatment by a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence OF CDRH, Office of Device Evaluation (ODE)

Prescription Use

OR

Over-the-Counter Use

(Optional Format 1-2-96)



(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033425

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