



Food and Drug Administration
10903 New Hampshire Avenue
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December 30, 2015

Carticept Medical, Inc.
c/o Ms. Rachel Kennedy
Regulatory and Clinical Research Institute
5353 Wayzata Blvd, Suite 505
Minneapolis, MN 55416

Re: K151255

Trade/Device Name: Navigator Aesthetic Delivery System (Navigator AE)
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: November 30, 2105
Received: December 1, 2015

Dear Ms. Kennedy:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Tina
Kiang -S

for Erin I. Keith, M.S.

Director

Division of Anesthesiology, General Hospital,

Respiratory, Infection Control and

Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K151255

Device Name
Navigator Aesthetic Delivery System (Navigator AE)

Indications for Use (Describe)

The Navigator™ AE is an infiltration pump used with the Cellfina handpiece to cause a flow of dilute Lidocaine from a bag for subcutaneous delivery of anesthetic into a patient in a manner controlled manually by a healthcare professional. The Navigator is not intended for use as an IV infusion pump.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Traditional 510(k) Summary

Submitted by: Carticept, Inc.

Contact Person: Carribeth Ramey
Vice President, Engineering
Carticept Medical, Inc.

Email: cramey@carticept.com

Date of Summary: December 30, 2015

Device Trade Name: Navigator Aesthetic Delivery System (Navigator AE)

Model Number: NAV-013 (FDM), NAV-014 (Foot Pedal Control), NAV-037 (Cassette), Software version 5.1.1.0

Product Code: FRN

Common or Usual Name: Infusion Pump, External

Classification Name: Infusion pump (21 CFR 880.5725)

Predicate Device(s): Carticept's Navigator DS (K124053)
HK Surgical's KleinTouch Pump (K123822)

Reference Predicate: The Cellfinal Aesthetic handpiece was cleared by FDA on April 14, 2014 as part of the Cabochon Aesthetics, Cabochon System, K134010.

Device Description: The Navigator AE is an optional fluid delivery mechanism for use with the Cellfina Aesthetic handpiece. The device is comprised of the following major components: (1) a fluid delivery module (pump drive unit); (2) a disposable cassette that is designed for single use; and, (3) a wired USB foot pedal. The Navigator AE components interface with a commercially available single-use handpiece and tubing set that is discarded following use on a specific patient.

Indication for Use:

The Navigator™ AE is an infiltration pump used with the Cellfina handpiece to cause a flow of dilute Lidocaine from a bag for subcutaneous delivery of anesthetic into a patient in a manner controlled manually by a healthcare professional. The Navigator is not intended for use as an IV infusion pump.

Predicate Indication for Use:

The KleinTouch Pump is an infiltration pump used to cause a flow of fluid from an IV bag into a patient in a manner controlled manually by a health care professional. The KleinTouch Pump is not intended to be used as an IV infusion pump.

The indications for the Navigator AE describe the intended application of the device, in contrast to the very general terms used in the predicate indication statement. These differences do not reflect an actual difference in the manner in which these devices are used, based on a review of labeling. For this reason, the differences do not impact safety and effectiveness of the device when used as labeled.

Rationale for Substantial Equivalence:

The Navigator AE is substantially equivalent to the HK Surgical KleinTouch Pump (K123822). The Navigator AE raises no new questions of safety or effectiveness as compared to the KleinTouch Pump. The Navigator AE has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the Navigator AE and its predicate devices raise no new issues of safety or effectiveness.

Technological Characteristics:

The Navigator AE fluid delivery module is a software-driven, microprocessor controlled electromechanical system that pulls fluids from an IV bag and pushes them through the cassette to a commercially available handpiece assembly for delivery to the patient. Delivery volumes and rates are programmed by the operator on an LCD touch screen display.

All aspects of the fluid delivery module are contained within a plastic housing that receives the system-dedicated, sterile, disposable cassette. Once installed, the cassette is the point of attachment for the commercially available per-patient tubing and handpiece set. The wired foot pedal control interfaces with the fluid pump via USB for wired control of fluid delivery. The system operates with user-provided disposable supplies, such as off-the-shelf IV bag(s) and tubing sets. (All technological aspects of the Navigator DS device are preserved with the exception of ultrasound imaging and over-pressure alarm features.)

Performance Testing Summary:

The following performance data was the basis for the a substantial equivalence determination:

- An assurance case was provided for the Navigator Aesthetic Delivery System, per the FDA guidance

document, Infusion Pumps Total Product Life Cycle.

The stated goal of the assurance case is to document that the design of the Navigator AE System is adequately safe for its intended use.

The assurance case defined the device system, including the indications for use, system specifications, use environments, and user population. The supporting assurance arguments covered the following attributes:

- Mitigation of device hazards, including infusion delivery errors, incorrect therapy, biological/chemical hazards, and traumatic injuries.
- Mitigation of hazardous situations
- Adequacy of risk management
- Device reliability
- System performance specifications are acceptable for the intended use
- Device is accurate under expected conditions of use

The following specific evidence was included within the assurance case:

Functionality

- Testing to characterize the system functionality over expected conditions of use, including fluidic properties and environmental characteristics.
- Flow rate characterization, accuracy of volumes dispensed, flow profiles and flow rate accuracy.
- Occlusion testing,
- Integrity of fluid pathway components.
- Reliability assessment
- Shipping studies per ISTA 2a

Software

- Device Software Version 5.1.1.0/5.1.1.0 was developed in accordance with EN 62304:2006 and evaluated as part of this 510(k) Submission.
- Documentation for Major Level of Concern software was provided, as recommended by the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.
- Software verification and validation testing, including software static analysis.
- Zero unresolved software anomalies were reported.

Electrical Safety and Electromagnetic Compatibility

- Electrical safety and electromagnetic compatibility were verified through testing in accordance with UL60601-1, IEC 60601-2-24 and IEC 60601-1-2.

Biological and Drug Compatibility

- Biocompatibility per ISO 10993-1
 - Cytotoxicity per ISO 10993-5
 - Sensitization per ISO 10993-10
 - Hemolysis per ISO 10993-4
 - Irritation per ISO 10993-10
 - Acute Systemic Toxicity per ISO 10993-11
- Extractables/leachables testing per ISO 10993-18, Biological evaluation of medical devices — Part 18: Chemical characterization of materials
- Drug compatibility and particulate analysis per USP <788> Particulate Matter in Injections

Sterility and Shelf Life

- The Navigator AE Cassettes are sterilized with Ethylene Oxide gas.
- Sterilization validation methodology in accordance with ISO 11135 was described.
- Ethylene oxide residuals for ethylene oxide and ethylene chlorohydrin specification limits were established per ISO 10993-7.
- Sterility Assurance Level is 10^{-6}
- Non-pyrogenic claims for the Navigator AE Cassettes were verified through Kinetic Chromogenic LAL and Material-Mediated Rabbit Pyrogen testing per ISO 10993 Biological evaluation of medical device - Part 11: Tests for systemic toxicity.
- A Shelf Life of 6 months was established with accelerated aging data per ASTM F1980. Testing verified package integrity (ASTM F88/F1929) and functional attributes of the Navigator AE Cassette remained within established specifications. A protocol for real-time aging was evaluated to assure ongoing stability.

Human Factors

- Simulated use/human factors studies – A Clinical Evaluation was determined not to be required for the Navigator AE. A simulated use study of human factors was conducted with intended users in the intended use environment that evaluated device performance, possible use error and user perception of difficulties with pump use. The study assessed the critical tasks or use scenarios where use related errors are most likely to occur.

The assurance case and referenced evidence demonstrate that the Navigator AE functions as designed and can be operated by the user as intended through the user interface and instructions provided.

Summary of Substantial

The performance data demonstrates that the Navigator

Equivalence

Aesthetic Delivery System is substantially equivalent to the named predicates.