K101194

JUL 11 2011

510(k) Summary

SUBMITTER'S INFORMATION

Owner:	Carticept Medical, Inc.
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Contact Person:	Tanya Eberle, Director, Regulatory Affairs
Date Summary Prepared:	May 23, 2011

DEVICE INFORMATION

Name of Device:	Navigator™ Delivery System (Navigator DS)
Common/Usual Name:	Infusion Pump, External
Classification Name:	Infusion Pump, Class II, 21 CFR 880.5725 (Product Code FRN)
Predicate Device(s):	Milestone Scientific's CompuFlo™ Infusion Pump (K053554)
Device Description:	The device consists of a fluid delivery module (motor driven piston syringe pump), a daily disposable cassette, a per-patient disposable handpiece and tubing set, and a wired foot pedal. The fluid delivery module delivers the medications or fluids from off-the-shelf vials via aspirated dispense. The user interface is via touch screen that allows the user to define per-delivery treatment volumes and regimens of off-the-shelf medications or fluids in accordance with their labeled indication and proposed dosage. Delivery of the user-defined regimen occurs through depression of the foot pedal that actuates dispense of the fluids through three individual fluid lines within the cassette. The fluid is then transported through the per-patient tubing and handpiece set where off-the-shelf needles are attached.
Indication for Use:	The Navigator™ Delivery System (Navigator DS) is intended for use in the delivery of medication and/or fluids in a controlled manner. The Navigator DS is indicated for use in the intermittent delivery of medications and other fluids in intra-articular applications.
Technological Characteristics:	The Navigator DS fluid delivery module is a motor-driven piston syringe pump that consists of three separate drives and independently calibrated force sensors. The fluid delivery module is a software-driven, microprocessor controlled electromechanical system that meters fluids through an administration set 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 sterile, per-patient tubing and handpiece set. The wired foot pedal provides control of delivery. The system operates with user-provided disposable supplies, such as off-the-shelf vials and off-the-shelf needles.

Comparison to Predicate Devices:

The Navigator DS is substantially equivalent to the Milestone CompuFlo Infusion Pump (K053554). The Navigator DS raises no new questions of safety or effectiveness as compared to the CompuFlo infusion pump. The Navigator DS 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 DS and its predicate devices raise no new issues of safety or effectiveness.

Performance Data:

Testing of the Navigator DS device was carried out to meet all elements of FDA's Draft Guidance "Total Product Life Cycle: Infusion Pump - Premarket Notification [5 10(k)] Submissions", including an Assurance Case Report and Hazard Analysis. A Risk Management Report demonstrated an acceptable risk profile based on design-based risk mitigation and satisfactory performance testing, including characterization of the system functionality over viscosity, temperature, and pressure extremes, flow rate characterization, accuracy of volumes dispensed, flow profiles and rate accuracy, occlusion testing, integrity of fluid pathway components, and software verification and validation. Additional safety evaluations related to performance included design verification and validation, sterilization validation, software validation, microbial ingress testing, viral ingress testing, dye ingress testing, cleaning validation, disinfection validation, biocompatibility, IPA residuals assessment, chemical compatibility and extractables/leachables testing with varying pH and polarity, simulated use/human factors studies, electrical safety testing, and shipping validations. A Clinical Evaluation was determined not to be required for the Navigator DS. 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 test results demonstrated that the Navigator DS functions as designed and can be operated by the user as intended through the user interface and instructions provided. The results demonstrate that the Navigator DS is as safe and effective and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Tanya Eberle
Director of Regulatory Affairs
Carticept Medical, Inc.
120 Windward Parkway, Suite 220
Alpharetta, Georgia 30005

JUL 11 2011

Re: K101194
Trade/Device Name: Navigator Delivery System (or Navigator DS)
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: June 2, 2011
Received: June 3, 2011

Dear Ms. Eberle:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) No. (if known): K101194

Device Name: Navigator™ Delivery System (Navigator DS)

Indications for Use: The Navigator™ Delivery System (Navigator DS) is intended for use in the delivery of medication and/or fluids in a controlled manner. The Navigator DS is indicated for use in the intermittent delivery of medications and other fluids in intra-articular applications.

Prescription Use: X AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

7/8/11

ivision Sign-Off)
vision of Anesthesiology, General Hospital
fection Control, Dental Devices

10(k) Number: K101194

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