DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 5, 2017

Entellus Medical Inc.
Karen Peterson
VP Clinical, Regulatory & Quality
3600 Holly Lane North, Suite 40
Plymouth, Minnesota 55447

Re: K163435
Trade/Device Name: Entellus Medical Reinforced Anesthesia Needle
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: BSP
Dated: February 24, 2017
Received: February 27, 2017

Dear Karen Peterson:

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" (21 CFR 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,

Tina Kiang -S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163435

Device Name
Entellus Medical Reinforced Anesthesia Needle

Indications for Use *(Describe)*
For use in injecting local anesthetics into a patient to provide regional anesthesia.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Date Prepared:	March 13, 2017
Submitter Information:	Entellus Medical, Inc. 3600 Holly lane North, Suite 40 Plymouth, MN 55447
Establishment Registration:	3006345872
Contact Information:	Karen E. Peterson Vice President Clinical, Regulatory and Quality (763) 463-7066 kpeterson@entellusmedical.com
Device Information:	
Trade Name:	Entellus Medical Reinforced Anesthesia Needle
Common Name:	Needle, Conduction, Anesthetic (w/wo introducer)
Classification Regulation:	21 CFR 868.5150
Classification Name:	Anesthesia conduction needle
Classification Panel:	Anesthesiology
Device Classification:	Class II
Product Code:	BSP
Predicate Device	BD Spinal Needle; Becton, Dickinson and Company [K091758]

Device Description:
The Entellus Medical Reinforced Anesthesia Needle is a 3.5” long disposable medical device that allows the user to transnasally administer anesthetic solutions. The Reinforced Anesthesia Needle device is a 27 gauge needle with a reinforcing sleeve which supports the needle to reduce needle flex during administration of anesthetic solutions. A slight bend at the distal end of the needle is designed to improve access to nasal anatomy. The Quincke tip extends approximately 2 mm past the reinforcing sleeve creating a distal stop. The needle hub features a standard luer-lock connector.

Reinforced Anesthesia Needle

Indications for Use/ Intended Use

For use in injecting local anesthetics into a patient to provide regional anesthesia

Contraindications:

None known.

Technological Characteristics:
The technological characteristics of the subject device are very similar to the predicate device [K091758], including: principle of operation, design, function, materials, biocompatibility and sterility.

Both the subject device and predicate device [K091758] are needles comprised of stainless steel cannulae attached to needle luer hubs comprised of plastic. They both provide a means to administer local anesthetic solutions to provide regional anesthesia. Both devices are provided sterile, single use only and are biocompatible per ISO 10993-1. Both device designs incorporate the same Quincke tip style, length, gauge, and luer hub. The subject device reinforcement is provided by a needle reinforcing sleeve whereas the predicate device [K091758] is reinforced by a stylet. The subject device has an 18 degree bend on the distal end whereas the predicate device [K091758] is provided straight.

Substantial Equivalence:
The indication for use and intended use of the subject device is similar to the predicate device [K091758]; the differences are semantic. The technological characteristics of the subject device are very similar to the predicate device [K091758], including: principle of operation, design, function, materials, biocompatibility, and sterility.

Performance Data:
Performance testing for the Reinforced Anesthesia Needle consisted of biocompatibility testing per ISO 10993-1, sterilization validation per ISO 11137-1, design verification, design validation, packaging, and shelf life per ISO 594-2, ISO 9626 and ISO 7864. Biocompatibility testing included cytoxicity, sensitization, intracutaneous reactivity, systemic toxicity, and pyrogen testing. Design verification included dimensional, functional, strength, and Human Factors Engineering & Usability Engineering (HFE/UE) testing. Design validation included HFE/UE testing. Animal and clinical testing were not performed. Performance testing showed that the device meets design specifications and performed as intended.

Conclusion
In conclusion, the subject device is substantially equivalent to the predicate device based on a comparison of intended use, indications for use, and technological characteristics. The subject device is as safe, as effective, and performs as well as or better than the predicate.