K103213

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510(k) Summary

This 510(k) Summary complies with the format and content requirements in 21 CFR 807.92.

Date Prepared: November 19, 2010

1. **Submitter Information**:

Entellus Medical, Inc.
6705 Wedgwood Court, North
Maple Grove, MN 55311

Establishment Registration: 3006345872

Contact Information: Karen E Peterson
Vice President Clinical, Regulatory and Quality
Phone: (763) 463-7066
kpeterson@entellusmedical.com

2. **Device Information:**

Trade Name:	FinESS™ Endoscope Sterilization Tray
Common Name:	Sterilization Tray
Classification Name:	Sterilization Wrap
Product Code:	KCT
Regulation Number:	Class II, 21 CFR 880.6850

3. **Predicate Device:**
Advance Sterilization Product APTIMAX STERILIZATION Tray and Accessories [K013003].

4. **Device Description:**
The FinESS Endoscope Sterilization Tray is comprised of a bottom, a clear lid, and silicone inserts designed to secure the FinESS Endoscope in place. The lid is clear and secured to the tray with a snap fit mechanism. The FinESS Endoscope Sterilization Tray contains perforations in the base and lid to allow the sterilant to penetrate. The use of commercially available sterilization wrap allows the tray to maintain sterility after sterilization.

5. **Intended Use**:
The FinESS Endoscope Sterilization Tray and the predicate device have the same intended use. Both devices are intended to encase instruments for sterilization when used with commercially available sterilization wrap.

The following is the "Indications For Use" for the FinESS Endoscope Sterilization Tray:

> The FinESS Endoscope Sterilization Tray is intended for use to encase and protect the FinESS Endoscope for sterilization in STERRAD 100NX using the standard cycle setting and NX Sterilization Systems using the advanced cycle setting.

- The sterilization cycle parameters of the STERRAD sterilizers are preset by the manufacturer and are not adjustable.
- The maximum product load per FinESS Endoscope Sterilization Tray includes 1 FinESS Endoscope and 2 light post adapters.

The FinESS Endoscope Sterilization Tray is intended to be used with legally marketed, FDA-cleared STERRAD compatible sterilization wrap in order to maintain sterility of the enclosed endoscope.

6. **Technological Characteristics**
The FinESS Endoscope Sterilization Tray and the predicate device have similar technological characteristics. Both devices consist of a rigid stable plastic container with lids that have been perforated to allow the penetration of sterilant. In both devices, perforations are found on the bottom and top of the tray thereby falling into the category of devices called "sterilization cassettes". Both devices require the use of a sterilization wrap to continue to maintain sterility during transportation and storage. To secure the device within the tray during sterilization, both devices have silicone inserts to hold the device in place. The materials of both devices are stable and do not degrade when exposed to multiple sterilization cycles.

7. **Performance Testing:**
Performance testing of the FinESS Endoscope Sterilization Tray consisted of design verification testing, biocompatibility and sterilization. Design verification testing included verification of device and material stability following repeated exposure to the sterilization cycle. Biocompatibility testing included primary dermal irritation and dermal sensitization post exposure to multiple sterilization cycles. Sterilization efficacy testing was conducted on the FinESS endoscope contained within the FinESS Endoscope Sterilization Tray to assure that an SAL of 10^{-6} could be achieved when used with the STERRAD NX and STERRAD 100NX sterilization system. In addition, sterilization testing of inoculated FinESS Endoscope Sterilization Tray and similarly inoculated Predicate tray showed that both devices are capable of allowing SAL of 10^{-6}. All results of the design verification, biocompatibility and sterilization testing met the acceptance criteria.

No clinical evaluations were conducted.

8. **Conclusion:**
The FinESS Endoscope Sterilization Tray is substantially equivalent to the predicate device, APTIMAX Instrument Tray [K013003]. The device has the same intended use, similar indication for use, and similar technological characteristics as the predicate device. Minor differences in the technological characteristics do not raise new questions of safety and efficacy. In addition, performance testing conducted demonstrate that the FinESS Endoscope Sterilization Tray is as safe and effective and performs as well as the predicate device.

Thus, the FinESS Endoscope Sterilization Tray is substantially equivalent to 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

Entellus Medical, Incorporated
C/O Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

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Re: K103213
Trade/Device Name: FinESS™ Endoscope Sterilization Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: January 14, 2011
Received: January 19, 2011

Dear Mr. Job:

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.

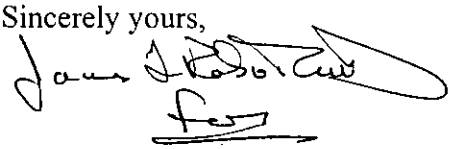
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

Enclosure

Indications for Use Statement

510(k) Number: _____

Device Name: FinESS™ Endoscope Sterilization Tray

Indications for Use:

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Prescription Use ____ _____ Over-the-Counter Use _X____
(21 CFR 801 Subpart D) AND/OR (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE—
CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Mansi-Wells

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

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