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K120474

JUL 10 2012

6) 510(k) Summary

510(k) Summary for
Gyrus ACMI Telescope Storage-Sterilization Tray

General Information

Manufacturer:	**Gyrus ACMI Inc.** **136 Turnpike Rd.** **Southborough, MA 01772-2104**
Establishment Registration Number:	**3003790304**
Contact Person:	**Graham Baillie** **Manager, Regulatory Affairs**

Device Description

Classification Name:	**Sterilization Wrap**
Product Code	**KCT**
Trade Name:	**Gyrus ACMI Telescope Storage-Sterilization Tray**
Generic/Common Name:	**Sterilization wrap containers, trays, cassettes & other accessories**

Predicate Device

K092682

Intended Use

The Gyrus ACMI Telescope Storage-Sterilization Tray (TEL-GT) is intended to be used to enclose and protect Gyrus ACMI telescopes during Steam Sterilization using the following parameters:

STEAM Sterilization Parameters:

	PreVacuum
Temp:	275°F
	132°C
Pressure	26psigs
Exposure	3 minutes
Dry Time	20 minutes

The trays are to be double wrapped with an FDA cleared sterilization wrap. The trays are optional accessories to the Gyrus ACMI telescopes. Telescopes without lumens up to 31 cm in length may be sterilized in the tray with a diameter between 2.7mm to 4mm. Two telescopes can be sterilized at one time.

Gyrus ACMI, Inc
136 Turnpike Road
Southborough, MA 01772
office 508.804.2600
fax 508.804.2624
www.gyrusacmi.com

GYRUS ACMI

Power through integration – Olympus

Maintenance of Sterility is dependent on the sterilization wrap shelf life and not the tray. User must follow the instructions for use supplied with the approved sterilization wrap and follow recommended storage conditions and timeframes for shelf life of the sterilization wrap.

Product Description

The Gyrus ACMI Telescope Storage-Sterilization Tray is a two-piece container made of a plastic lid containing 14 holes, and a plastic tray containing 18 holes that permit ready ingress of Steam. The tray provides protection to the telescopes during sterilization and storage.

Design

Compliance to Voluntary Standards

The design of the DEVICE complies with the following standards: ISO10993-1, AAMI/ANSI ST77, AAMI/ANSI ST79

Material

The DEVICE does not come into contact with patients. The materials used are the same as the materials in the predicate devices, as well as other legally marketed devices manufactured by Gyrus ACMI. Materials are compatible with testing identified in ISO10993-1.

Summary of Sterilization and Shelf Life Discussion

The DEVICE was validated to sterilize Gyrus ACMI telescopes using Steam with the following parameters:

	PreVacuum
Temp:	275°F
	132°C
Pressure	26 psigs
Exposure	3 minutes
Dry Time	20 minutes

Maintenance of Sterility is dependent on the sterilization wrap shelf life and not the tray. User must follow the instructions for use supplied with the sterilization wrap and follow manufacturers recommended storage conditions and timeframes for shelf life of the sterilization wrap.

Technological Characteristics and Substantial Equivalence

The Gyrus ACMI Telescope Storage-Sterilization Tray is composed of the same materials as the predicates and utilizes the same features as the predicates. Validation testing was performed to ensure sterility of devices recommended for use with the proposed device.

Conclusion:

In summary, based on intended use, technological characteristics and performance data, the Gyrus ACMI Telescope Storage-Sterilization Tray is substantially equivalent to previously cleared Gyrus ACMI storage-sterilization trays.

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

Mr. Graham Baillie
Manager, Regulatory Affairs
Gyrus ACMI, Incorporated
136 Turnpike Road
Southborough, Massachusetts 01772

JUL 10 2012

Re: K120474
Trade/Device Name: Gyrus ACMI Telescope Storage-Sterilization Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: June 14, 2012
Received: June 15, 2012

Dear Mr. Baillie:

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,

For

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

K120474

5) **Indications for Use Statement**

Statement of Intended Use

510(k) Number (if Known): _____

Device Name: Gyrus ACMI Telescope Storage-Sterilization Tray

Indications For Use:

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Maintenance of Sterility is dependent on the sterilization wrap shelf life and not the tray. User must follow the instructions for use supplied with the sterilization wrap and follow manufacturers recommended storage conditions and timeframes for shelf life .

Prescription Use ____ And/Or Over the Counter Use _X_

(21 CFR Part 801 Subpart D) (21 CFR Part 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. Claverie-Wall

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

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