JAN 1 1 2012

STERIS®

510(k) Summary
For
STERIS STEAM π

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (440) 354-2600
Fax No: (440) 357-9198

Contact: Bill Brodbeck
Senior Manager, Regulatory Affairs
Telephone: (440) 392-7690
Fax No: (440) 357-9198

Summary Date: January 4, 2012

1. Device Name

Indicators Models:	STERIS STEAM π
Common Name:	Chemical Indicator
Classification Name:	Physical/chemical sterilization process indicators (21 CFR 880.2800 (b), Product Code JOJ)

2. Predicate Device

- Verify STEAM Value Indicators (K060103)

3. Device Description

The proposed STERIS STEAM π is composed of a single ink printed on polyethylene terephthalate. The indicator inks change from pink to copper color when exposed to temperature ranges of 121°C to 135°C (250°F to 275°F).

4. Intended Use

The STERIS STEAM π is process indicator that undergoes a visual color change from a pink to copper color when exposed to the following steam sterilization cycle parameters:

- 121°C (250°F), 30 min, steam sterilization gravity cycle
- 132°C (270°F), 15 min, steam sterilization gravity cycle
- 135°C (275°F), 10 min, steam sterilization gravity cycle
- 132°C (270°F), 4 min, steam sterilization dynamic air removal cycle
- 135°C (275°F), 3 min, steam sterilization dynamic air removal cycle

5. Description of Safety and Substantial Equivalence

The proposed and predicate devices are both single use indicators for use in steam sterilization cycles. The differences between the proposed STERIS STEAM π Indicators and the predicate device are limited to differences in general design of the ink and material. However, these differences do not affect the intended use, performance characteristics, nor do the differences raise any new issues of safety and efficacy.

6. **Performance Testing**

Performance testing was conducted to verify that the proposed STERIS STEAM π meets the requirements for process [Class 1] indicators as defined in ANSI/AAMI ISO 11140-1:2005 using a resistometer to ANSI/AAMI ISO 18472. The data provided by this testing demonstrates that the proposed STERIS STEAM π device 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

Mr. Robert Sullivan
Senior Director, FDA Regulatory Affairs
STERIS Corporation
5960 Heisley Road
Mentor, Ohio 44060

JAN 1 1 2012

Re: K112256
Trade/Device Name: STERIS STEAM π
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: January 4, 2012
Received: January 5, 2012

Dear Mr. Sullivan:

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

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

510(k) Number (if known): K112256

Device Name: STERIS STEAM π

Indications for Use:

The STERIS STEAM π is a process indicator that undergoes a visual color change from a pink to brown color when exposed to the following steam sterilization cycle parameters:

- 121°C (250°F), 30 min, steam sterilization gravity cycle
- 132°C (270°F), 15 min, steam sterilization gravity cycle
- 135°C (275°F), 10 min, steam sterilization gravity cycle
- 132°C (270°F), 4 min, steam sterilization dynamic air removal cycle
- 135°C (275°F), 3 min, steam sterilization dynamic air removal cycle

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (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 T. Claverie-Williams

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

510(k) Number: K112256

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