K111453

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APR - 5 2012

510(k) Summary

Submitted by Propper Manufacturing Company, Inc.
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Contact Name: Andrew Sharavara

Date Submitted: May 25, 2011

Trade Name: Steam Dot Blu® Process Indicator
Common Name: Chemical Sterilization Process Indicator

Product Code / Regulation: JOJ / 21 C.F.R. 880.2800

Description: Steam Dou Blu® Process Indicator is a single use chemical sterilization indicator for steam sterilizers. It complies with the requirements established in the FDA guidance document "Premarket Notification [510(k)] Submissions for Chemical Indicators," issued on December 19, 2003 and "ANSI/AAMI/ISO 11140-1:2005, Sterilization of health care products – Chemical indicators – Part 1: General requirements" standard for process indicators.
Steam Dot Blu® Process Indicator is designed to be used in 121°C gravity and in 132°C, 134°C and 135°C pre-vacuum steam sterilization cycles. During sterilization cycles the indicator change color from blue to pink. The color change after processing is stable. No lead or heavy metals or their compounds are added in the production of the indicator.

Intended Use: Steam Dot Blu® Process Indicator is a chemical sterilization indicator intended to be used by a health care provider with sterilization wraps, containers, cassettes, pouches or other packaging materials to distinguish between processed and unprocessed units.
The indicator changes color from blue to pink when exposed to steam sterilization conditions at 121°C in gravity displacement and 132°C, 134°C, and 135°C in pre-vacuum cycles. The performance of the Steam Dot-Blu® Process Indicator meets the requirements of ANSI/AAMI/ISO 11140-1:2005 for process (Class 1) indicators.
No lead or heavy metals or their compounds are added in the production of the indicator.

Substantial Equivalence: The Steam Dot Blu® Process Indicator is similar in intended use and operating characteristics to the following indicators:

Predicate device	**510k number**
Propper Steam Dot™ Indicator	Pre-amendment

Substantial equivalence to the predicate device was evaluated according to the FDA guidance document "Premarket Notification [510(k)] Submissions for Chemical Indicators," issued on December 19, 2003, and technological parameters have been tested according to the FDA recognized consensus standard ANSI/AAMI/ISO 11140-1:2005, Sterilization of health care products – Chemical indicators – Part 1: General requirements.

The proposed and predicate devices are single-use chemical indicators designed to distinguish between steam processed and unprocessed items. The Steam Dot Blu® Process Indicator is similar with respect to indications for use and operating characteristics to the predicate devices in terms of 510(k) substantial equivalency. The differences between the new device and predicate devices are limited to differences in materials, and colors of unprocessed indicators and indicators after steam exposure and those differences do not raise any new issues of safety and efficacy.

Conclusion: Test results demonstrate that Steam Dot Blu® Process Indicator is equivalent to the predicate device and therefore should be allowed for market in the United States.

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

Dr. Andrew Sharavara
Chief Technical Officer and R&D Director
Propper Manufacturing Company, Inc.
36-04 Skillman Avenue
Long Island City, New York 11101

APR - 5 2012

Re: K111453
Trade/Device Name: Steam Dot Blu® Process Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: March 29, 2012
Received: April 2, 2012

Dear Dr. Sharavara:

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

510(k) Number (if known): _____

Device Name: Steam Dot Blu® Process Indicator

Intended Use:

Steam Dot Blu® Process Indicator is a chemical sterilization indicator intended to be used by a health care provider with sterilization wraps, containers, cassettes, pouches or other packaging materials to distinguish between processed and unprocessed units.
The indicator changes color from blue to pink when exposed to steam sterilization conditions at 121°C in gravity displacement and 132°C, 134°C and 135°C in pre-vacuum cycles.
The performance of the Steam Dot-Blu® Process Indicator meets the requirements of ANSI/AAMI/ISO 11140-1:2005 for process (Class 1) indicators.
No lead or heavy metals or their compounds are added in the production of the indicator.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __X__ (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. Claxton-Will

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

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