

K162894

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510(k) Summary

MAY 25 2011

Submitted by Propper Manufacturing Company, Inc.
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Long Island City, New York 11101
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Contact Name: Andrew Sharavara

Date Submitted: September 27, 2010

Trade Name: Emu-Chex™ Sterilization Indicator
Common Name: Chemical Sterilization Process Indicator

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

Description: The Emu-Chex™ Sterilization Indicator is a chemical sterilization indicator for steam sterilizers that complies with ANSI/AAMI/ISO 11140-1:2005, Sterilization of health care products – Chemical indicators – Part 1: General requirements, emulating indicators. The variety of Emu-Chex™ sterilization indicators includes those for use in a gravity steam sterilization process operating at 121°C for 20 minutes, for use in pre-vacuum steam sterilization process operating at 132° C for 4 minutes and 135° C for 3 minutes. No lead or heavy metals or their compounds are added in the production of the indicator.

Intended Use: The Emu-Chex™ Sterilization Indicator is an emulating indicator intended to be used by a health care provider to monitor steam sterilization processes. Emu-Chex™ Sterilization Indicator comes in three varieties: for use in a gravity steam sterilization process operating at 121°C for 20 minutes, for use in pre-vacuum steam sterilization processes operating at 132° C for 4 minutes and 135° C for 3 minutes.

The Emu-Chex™ Sterilization Indicators can be placed together with items to be steam sterilized. The indicator changes color from blue-green to brown when the sterilization cycle is complete. The performance of the Emu-Chex™ Sterilization Indicator meets the requirements of ANSI/AAMI/ISO 11140-1:2005 for emulating indicators.

Substantial Equivalence: The Emu-Chex™ Sterilization Indicator is similar in intended use and operating characteristics to the following indicators:

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Emu-Chex version	Predicate device	510k number
121°C – 20 min	Propper Vapor Line indicator	K895910
132°C – 4 min	Steris Verify indicator	K071895
135°C – 3 min	Steris Verify indicator	K070461

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 for monitoring steam sterilization cycles. The Emu-Chex™ Sterilization 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 design, materials, and colors of unprocessed indicators and end-point reaction and those differences do not raise any new issues of safety and efficacy.

Conclusion: Test results demonstrate that Emu-Chex™ Sterilization Indicator is equivalent to the predicate devices and therefore should be allowed for market in the United States.



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, Incorporated
36-04 Skillman Avenue
Long Island City, New York 11101

MAY 25 2011

Re: K102894
Trade/Device Name: Emu™-Chex Sterilization Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: April 26, 2011
Received: May 2, 2011

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.

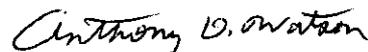
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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" (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 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): k102894

Device Name: Emu-Chex™ Sterilization Indicator

Intended Use:

The Emu-Chex™ Sterilization Indicator is an emulating indicator intended to be used by a health care provider to monitor steam sterilization processes. Emu-Chex™ Sterilization Indicator comes in three varieties: for use in a gravity steam sterilization process operating at 121°C for 20 minutes, for use in pre-vacuum steam sterilization processes operating at 132° C for 4 minutes and 135° C for 3 minutes.

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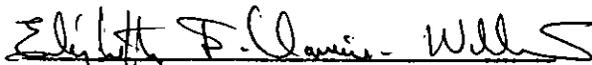
Prescription Use _____
(Part 21 CFR 801 Subpart D)

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)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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