K110369

510(k) Summary Statement (as required by 807.92 (c))

MAY - 6 2011

Date of Submission: January 14, 2011

Submitter:

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Establishment Registration NO: 1450962

Official Contact:

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Phone: (847) 928-1050
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Trade Name: Indistrip Green

Common Name: Process Indicator for Steam Sterilization

Device Classification:

Device indicator, physical/chemical sterilization process

Regulation Description Sterilization process indicator.

Regulation Medical Specialty General Hospital

Review Panel General Hospital

Product Code JOJ

Submission Type 510(k)

Regulation Number 880.2800

Device Class 2

Total Product Life Cycle (TPLC) TPLC Product Code Report
GMP Exempt? No

Predicate Device: Indistrip 400S; 510(k) No. K875193

Indications for Use:

For use as an internal or external chemical indicator to monitor exposure to steam sterilization conditions for: 121°C (250°F) @ 30 minutes in gravity steam sterilizer cycles or @ 134°C (273°F) for 4 minutes in gravity or vacuum assisted steam sterilizer cycles.

Consensus Standards: Utilized as part of our Statement of Conformity

Recognition Number: 14-195 Product Area: Sterility

Title of Standard: Sterilization of health care products - Chemical indicators - Part 1: General requirements, 2ed (Revision of ANSI/AAMI ST60:1996)

Reference Number: 11140-1:2005 Publication Date: 09/08/2009

Standards Development Organization: AAMI ANSI ISO

Device Description:

The INDISTRIP Green Process Indicator for sterilization consists of a metal free indicator ink printed onto white vellum. The indicator changes color from yellow to black when exposed to steam sterilization conditions. Unprocessed indicators are stable for atleast 6 months when stored at 30°C or less. The postprocessed indicator color is stable for at least 6 months after exposurer to steam sterilization conditions for: 121°C (250°F) @ 30 minutes in gravity steam sterilizer cycles or @ 134°C (273°F) for 4 minutes in gravity or vacuum assisted steam sterilizer cycles.

The indicator does not respond to dry heat or ethylene oxide. The process requirements, in comparison to the predicate device are presented in Table 5-TI.

Comparison with Predicate Device (Table 5-TI):

Item	Predicate Device	Subject Device
Name	Indistrip (K875193)	Indistrip Green
Intended Use	For use as an internal or external chemical indicator to monitor exposure to steam sterilization conditions for 121-141°C (250 – 285°F) gravity and vacuum assisted steam sterilizer cycles.	For use as an internal or external chemical indicator to monitor exposure to steam sterilization conditions for: 121°C (250°F) @ 30 minutes in gravity steam sterilizer cycles or @ 134°C (273°F) for 4 minutes in gravity or vacuum assisted steam sterilizer cycles.
Material	Lead Based Ink Printed onto White Vellum	Organic Based Ink, Metal Free, Printed onto White Vellum
Color Change	Off-White/tan to Black	Yellow to Black
Sterilization Method	Steam	Steam
Color Change Timing	8 minutes 250°F 3 minutes 273°F	8 minutes 250°F 3 minutes 273°F
Size	9/16" x 4"	9/16" x 4"
Precautions	Do not use the Indistrip to monitor dry heat, ethylene oxide, or other low temperature sterilization processes	Do not use the Indistrip Green to monitor dry heat, ethylene oxide, or other low temperature sterilization processes
General Instructions	Utilize on and/or in each pack to be steam sterilized. Process according to established procedures. After processing remove the indicator and observe the color change. If the indicator bar is not black, inadequate exposure is indicated. Return for processing.	Utilize on and/or in each pack to be steam sterilized. Process according to established procedures. After processing remove the indicator and observe the color change. If the indicator bar is not black, inadequate exposure is indicated. Return for processing.

Performance Data:

Meats the requirements defined in 11140-1:2005 (AAMI ANSI ISO) Class 1 Table 5-TII Test Performance Characteristics Class 1 Process Indicators

Test Environment	Test Time	Test Temperature	No Change or a change that is markedly different from the visible color change as specified by the manufacturer	Visible color change as specified by the manufacturer	Indistrip Results	Indistrip Green Results
Saturated Steam	3.0 min ± 5 s	121 °C (+3/0 °C)	Acceptable result	Unacceptable result	Pass	Pass
Saturated Steam	10.0 min ± 5 s	121 °C (+3/0 °C)	Unacceptable result	Acceptable result	Pass	Pass
Saturated Steam	0.5 min ± 5 s	134 °C (+3/0 °C)	Acceptable result	Unacceptable result	Pass	Pass
Saturated Steam	2.0 min ± 5 s	134 °C (+3/0 °C)	Unacceptable result	Acceptable result	Pass	Pass
Dry Heat	30 min ± 1 s	140 °C (+2/0 °C)	Acceptable result	Unacceptable result	Pass	Pass

Conclusion:

The Indistrip Green, Heavy Metal free Steam Sterilization indicator is in accordance with 21 CFR 807 has the same intended use, provides substantially equivalent process color change timing, and color change stability as the Indistrip steam sterilization predicate device 510(k) K875193. The main difference is that the Indistrip Green, Product Code IND400G indicator ink is developed with a metal free organic indicator as compared to the standard lead based steam indicator utilized in the Indistrip 400S steam indicator strip. The two devices are substantially equivalent.

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. Mark Espenscheid
Director of Quality
Indilab, Incorporated
10367 Franklin Avenue
Franklin Park, Illinois 60131

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Re: K110369
Trade/Device Name: Indistrip Green
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: January 15, 2011
Received: February 8, 2011

Dear Mr. Espenscheid:

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.

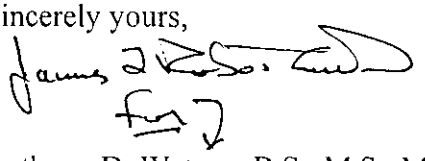
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

Section 4 - Indications for Use Statement.

510(k) Number (if known): N/A

Device Name: Indistrip Green

Indications for Use:

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For use as an internal or external chemical indicator to monitor exposure to steam sterilization conditions for: 121°C (250°F) @ 30 minutes in gravity steam sterilizer cycles or @ 134°C (273°F) for 4 minutes in gravity or vacuum assisted steam sterilizer cycles.

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 ANTOHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth T. Claverie-Wells

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

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