K101528

**Premarket Notification (510(k)) Summary**

OCT 1 2010

3M

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|---|---|
| **Sponsor Information:** | 3M Health Care<br>3M Center, Bldg. 275-5W-06<br>St. Paul, MN 55144-1000 |
| Contact Person: | Suzanne Leung, Ph.D.<br>Regulatory Affairs |
| Phone Number: | (651) 575-8052 |
| FAX Number: | (651) 736-0897 |
| Date of Summary: | September 28, 2010 |

**Device Name and Classification:**

| | |
|---|---|
| Common or Usual Name: | Sterilization Process Indicators for Steam |
| Proprietary Name: | 3M™ Comply™ Process Indicators for Steam |
| Classification Name: | Indicator, Physical/Chemical Sterilization Process<br>(21 CFR § 880.2800(b)) |

**Predicate Device:**

3M™ Comply™ Autoclave Tape

**Description of Device:**

The 3M™ Comply™ Lead Free Process Indicators for Steam provides immediate identification of processed items. The chemical indicator ink does not contain lead as part of the reaction chemistry and can be printed onto suitable paper substrates. As an example, the ink is printed onto adhesive-coated crepe paper for autoclave tape, onto cardstock for record cards, and onto adhesive-coated labelstock for indicator labels on test packs.

The purpose of this submission is to:

- Replace the lead ink in the current 3M™ Comply™ Autoclave Tape with Lead Free Ink. The current Comply Autoclave Tape was cleared under K932129
- Apply the Lead Free Ink to cardstock as a new 3M™ Comply™ Record Card
- Replace the lead ink in the process indicators on the labels currently used to secure all 3M™ Comply™ test packs. The use of the Lead Free Ink in process indicators on labels securing the Lead Free Bowie Dick test pack was cleared under K093199. This filing will extend its use to other test packs for steam.

**Indications for Use:**

The 3M™ Comply™ Lead Free Process Indicators for Steam are designed to demonstrate that the unit or load has been exposed to a steam sterilization process and to distinguish between processed and unprocessed units or loads.

3M Comply Lead Free Process Indicators for Steam include:

- Comply 68200 Lead Free Record Card
- Comply 1322 Lead Free Indicator Tape
- Lead Free Test Pack Labels to be used on test packs including the following -
  - Comply 41380 Steam-Plus Test Pack
  - Comply 41360 Steam Test Pack
  - 3M Attest™ 1276 Steam Test Pack
  - 3M Attest™ 1296 Steam Test Pack
  - 3M Attest™ 41382 Steam-Plus Test Pack
  - Comply 1233LF, 00132LF, 00135LF Bowie Dick Test Packs

Use the 3M™ Comply™ Lead Free Process Indicators for Steam in steam sterilization processes described below.

| Cycle Type | Temperature | Exposure Time |
|---|---|---|
| Gravity | 250 °F/121 °C | ≥ 30 minutes (wrapped) |
| Gravity | 270 °F/132 °C | ≥ 3 minutes (unwrapped)<br>≥ 15 minutes (wrapped) |
| Gravity | 275 °F/135 °C | ≥ 3 minutes (unwrapped)<br>≥ 10 minutes (wrapped) |
| Vacuum-assisted (prevacuum) | 270 °F/132 °C | ≥ 3 minutes (unwrapped)<br>≥ 4 minutes (wrapped) |
| Vacuum-assisted (prevacuum) | 273 °F/134 °C | ≥ 3.5 minutes (unwrapped)<br>≥ 4 minutes (wrapped) |
| Vacuum-assisted (prevacuum) | 275 °F/135 °C | ≥ 3 minutes (wrapped or unwrapped) |

**Comparative Data for Determining Substantial Equivalence of New Device to Predicate Device:**

Results from testing that was conducted met the process indicator requirements of FDA's *Premarket Notification [510(k)] Submissions for Chemical Indicators: Guidance for Industry and FDA Staff*, December 19. 2003 and ANSI/AAMI/ISO 11140-1:2005 *Sterilization of health care products – Chemical indicators, Part 1: General Requirements.* The 3M™ Comply™ Lead Free Process Indicators are substantially equivalent to the predicate device 3M™ Comply™ Autoclave Tape, cleared under K932129 in terms of intended use, performance, physical properties and technological characteristics. There are no new questions of safety or effectiveness.

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

Suzanne Leung, Ph.D.
Regulatory Affairs
3M Health Care
3M Center, Building 275-5W-06
St. Paul, Minnesota 55144-1000

OCT 1 2010

Re: K101528
Trade/Device Name: 3M™ Comply™ Lead Free Process Indicators for Steam
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: September 16, 2010
Received: September 20, 2010

Dear Dr. Leung:

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:** K101528
**Device Name:** 3M™ Comply™ Lead Free Process Indicators for Steam

**Indications for Use:**

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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 A. Claverie Wills

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

510(k) Number: K101528