510(k) Summary

K101249

SEP 08 2010

Sponsor Information:

3M Health Care
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

Contact Person:	Suzanne Leung Regulatory Affairs
Phone Number:	(651) 575-8052
FAX Number:	(651) 736-0897

Date of Summary: August 16, 2010

Device Name and Classification:

Common or Usual Name:	Sterilization Process Indicators for Steam
Proprietary Name:	3M™ Comply™ SteriGage™ 1243RA, 1243RB, and 1243RE Chemical Integrators for Steam
Classification Name:	Indicator, Physical/Chemical Sterilization Process (21 CFR § 880.2800(b))
Performance Standards:	There are no mandatory performance standards

Predicate Device:

3M™ Comply™ SteriGage™ Chemical Integrator (formerly InfoChem SteriGage™ Chemical Integrator)

Description of Device:

3M Comply SteriGage 1243RA, 1243RB, and 1243RE Steam Chemical Integrators are single-use chemical indicators consisting of a paper wick and steam and temperature sensitive chemical pellet contained in a paper/film/foil laminate. The chemical pellet melts and migrates as a dark color along the paper wick. The migration is visible through a window marked ACCEPT or REJECT; the extent of migration depends on steam, time, and temperature.

Indications for Use:

The 3M™ Comply™ SteriGage™ 1243RA, 1243RB, 1243RE Chemical Integrators for Steam are designed for pack control monitoring of the following cycles.

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

The Minimum Stated Values for SteriGage as determined using a resistometer are shown below.

Minimum Stated Values for SteriGage

250° F 121° C	270° F 132° C	273° F 134° C	275° F 135° C
16.5 minutes	2.0 minutes	1.4 minutes	1.1 minute

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

Testing on multiple lots confirmed that the new model of 3M™ Comply™ SteriGage™ Chemical Integrator for Steam complies with the chemical integrator performance 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 (for Class 5).* Stated values were obtained

using a test vessel compliant to ANSI/AAMI/ISO 18472:2006 *Sterilization of Health Care Product-Biological and Chemical Indicators: Test Equipment.*

Summary of Nonclinical Testing

Test	Acceptance Criteria	Results
Stated Values in Resistometer	See Minimum Stated Values	Passed
Dry Heat	Shows 'Reject' at 137 – 138 °C, 30 min	Passed
Comparison to BI	Shows 'Reject' at conditions where BI fails, Shows 'Accept' only at conditions where BI passes	Passed
Endpoint Stability	An 'Accept' result or a 'Reject' result does not change after storage for 6 months	Passed

The testing summarized above showed that the new model of 3M™ Comply™ SteriGage™ Chemical Integrator for Steam is substantially equivalent to the predicate device, the current 3M™ Comply™ SteriGage™ Chemical Integrator, cleared under K771080 in terms of design, intended use, indications for use, composition, physical properties and technological characteristics. The only difference between the predicate and the new integrators is the change in the shape of the product from trapezoidal to rectangular. 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 Company
3M Center, Building 275-05-W-06
Saint Paul, Minnesota 55144-1000

SEP 0 8 2010

Re: K101249
Trade/Device Name: 3M™ Comply™ SteriGage™ 1243RA, 1243RB, and 1243RE
Chemical Integrators for Steam
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: August 30, 2010
Received: August 31, 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,

for

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

K101249

SEP 0 8 2010

Indications for Use

510(k) Number (if known): K101249

Device Name: 3M™ Comply™ SteriGage™ 1243RA, 1243RB, and 1243RE Chemical Integrators for Steam

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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 F. Claverie - W

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

510(k) Number: K101249