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APPENDIX G: Premarket Notification (510 (k)) Summary

K013228

Manufacturer:

3M Company
3M Medical-Surgical Division
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

Regulatory Affairs Contact:

Gretchen Keenan, RAC
Product Regulation Manager
3M Company
Tel: 651-733-7605

Date Summary Prepared:

September 26, 2001

Device Trade Name:

3M™ Comply™ 1248 Gas Plasma Chemical Indicator

Common or Usual Name:

Chemical Indicator

Classification:

Physical/Chemical Sterilization Process Indicator
[21CFR 880.2800(b)]

Device Description:

The 3M Comply 1248 Gas Plasma Chemical Indicator is a sterilization process indicator and is comprised of a blue chemical indicator ink bar printed on a white plastic strip. A comparison color match is also printed on the plastic strip, below the blue indicator ink bar. The chemical indicator changes color from blue to pink upon exposure to vapor hydrogen peroxide in the STERRAD®100, STERRAD®100S and the STERRAD®50 Sterilization processes.

Intended Use:

The 3M Comply 1248 Gas Plasma Chemical Indicator is indicated for use as an internal pack process indicator to indicate exposure to vapor hydrogen peroxide in the STERRAD® 100, STERRAD® 100S, and STERRAD® 50 Sterilization processes.

Substantial Equivalence:

The 3M Comply 1248 Gas Plasma Chemical Indicator Strip is substantially equivalent to the Advanced Sterilization Products (ASP) STERRAD® Gas Plasma Chemical Indicator Strip (K921910). The 3M Comply 1248 Gas Plasma Chemical Indicator and the predicate device share the same intended use of internal pack sterilization process indicators to indicate exposure to vapor hydrogen peroxide in the STERRAD 100, STERRAD 100S, and the STERRAD 50 sterilization processes. In addition, the 3M Comply 1248 Gas Plasma Chemical Indicator and the predicate device share similar design and appearance.

Testing Summary:

TEST:	*RESULT:*
Cycle Conditions Required for Color Change in a STERRAD 100 Sterilizer	Testing verified that the Comply™ 1248 Gas Plasma Chemical Indicators turned from blue to pink when exposed to the STERRAD 100 Sterilization cycle and the minimum time required for all indicators to indicate a "pass" in relation to the color match was found to be

	between 10 and 15 minutes.
Cycle Conditions Required for Color Change Using the STERRAD 100S Cycle	Testing verified that the Comply™ 1248 Gas Plasma Chemical Indicators turned from blue to pink when exposed to the STERRAD 100S Sterilization cycle and the minimum time required for all indicators to indicate a "pass" in relation to the color match was found to be between 4 and 8 minutes.
Cycle Conditions Required for Color Change in a STERRAD 50 Sterilizer	Testing verified that the Comply™ 1248 Gas Plasma Chemical Indicators turned from blue to pink when exposed to the STERRAD 50 Sterilization cycle and the minimum time required for all indicators to indicate a "pass" in relation to the color match was found to be between 0.25 and 2.0 minutes.
Two-Year Stability Study	One-month interim results verified that all indicators turned from blue to pink when exposed to the complete STERRAD 100S Sterilization cycles with a hydrogen peroxide diffusion time of 16 minutes as well as the cycles cancelled after 12-minutes of hydrogen peroxide diffusion, thereby confirming the continued stability of the Comply™ 1248 Gas Plasma Chemical Indicator to date. Two-year stability testing is ongoing.
Open-Pouch Stability Testing	One-month interim results verified that all indicators turned from blue to pink when exposed to the complete STERRAD 100S Sterilization cycles with a hydrogen peroxide diffusion time of 16 minutes as well as the cycles cancelled after 12 minutes of hydrogen peroxide diffusion, thereby confirming the continued stability of the Comply™ 1248 Gas Plasma Chemical Indicator following opening the package, to date. Eight-week open-pouch stability testing is ongoing.
Light Stability Testing	Testing verified that the processed and unprocessed 3M Comply 1248 Gas Plasma Chemical Indicators retained their color after four (4) weeks of exposure to fluorescent light.
Performance After Exposure to Light	Testing verified that all indicators continued to meet the color match when exposed to both the complete STERRAD 100S Sterilization cycles with a hydrogen peroxide diffusion time of 16 minutes as well as the 12-minute cancelled cycles, thereby confirming the stability of the Comply™ 1248 Gas Plasma Chemical Indicator following four (4) weeks of exposure to fluorescent light.
Effect of the Absence of Hydrogen Peroxide on the Color Change	Testing verified that the Comply 1248 Gas Plasma Chemical Indicators did not exhibit any color change following exposure to a cycle containing deionized water instead of hydrogen peroxide.
Effects of Steam and Ethylene Oxide Sterilization	Testing verified that the Comply 1248 Gas Plasma Chemical Indicators were found to be unaffected by the ethylene oxide sterilization process and were grossly deformed while retaining the blue color of the indicator by the steam sterilization process. The Instructions For Use includes a Precaution not to use the indicators to monitor steam or ethylene oxide sterilization cycles.
Effects of Acid and Base	Testing verified that the Comply 1248 Gas Plasma Chemical Indicators were not sensitive to the presence of an acidic environment. The processed indicators were not sensitive to a basic environment. The

unprocessed color of the 3M Comply 1248 Gas Plasma Chemical Indicator was found to be sensitive to the presence of a basic (alkaline) environment. The Instructions For Use includes a Precaution to store the indicators away from alkaline chemicals.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 8 2002

Minnesota Mining and Manufacturing Company
C/O Ms. Tierney Norsted
Vice President
Regulatory & Clinical Research Institute, Inc
5353 Wayzata Boulevard, Suite 505
Minneapolis, Minnesota 55416

Re: K013228
Trade/Device Name: 3M™ Comply™ 1248 Gas Plasma Chemical Indicator
Regulation Number: 880.2800
Regulation Name: Indicator, Physical/Chemical Sterilization Process
Regulatory Class: II
Product Code: JOJ
Dated: December 12, 2001
Received: December 13, 2001

Dear Ms. Norsted:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX C: INDICATIONS FOR USE STATEMENT

510(k) Number: K013228

Device Name: 3M™ Comply™ 1248 Gas Plasma Chemical Indicator

Indications For Use: The 3M™ Comply™ 1248 Gas Plasma Chemical Indicator is indicated for use as an internal pack process indicator to verify exposure to vapor hydrogen peroxide in the STERRAD® 100, STERRAD® 100S, and STERRAD® 50 Sterilization processes. The chemical indicator bar turns from blue to pink after exposure to vapor hydrogen peroxide in these sterilization processes.

Chan S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013228