K020589

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

Manufacturer:

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

Regulatory Affairs Contact:

Joann L. Huehn
Advanced Regulatory Affairs Associate
3M Company
Tel: 651-733-9209
FAX: 651-737-5320

Date

February 21, 2002

Summary Prepared:

Device Trade Name:

3M™ Comply™ 1228 Gas Plasma Indicator Tape

Common or Usual Name:

Chemical Indicator Tape

Classification:

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

Device Description:

The 3M Comply™ 1228 Gas Plasma Indicator Tape is a sterilization process indicator and is comprised of non-cellulosic plastic backing material with a pressure sensitive adhesive on one side and indicator stripes on the other side. A color match is printed in the Comply 1228 Technical Information Sheet. The chemical indicator stripes turn from blue to pink after exposure to vapor hydrogen peroxide in the STERRAD® 100, STERRAD® 100S and the STERRAD® 50 Sterilization processes.

Intended Use:

The 3M Comply™ 1228 Gas Plasma Indicator Tape is indicated for use to secure packs and as an external pack process indicator to differentiate processed from unprocessed items when exposed to vapor hydrogen peroxide in the STERRAD® 100, STERRAD® 100S, and STERRAD® 50 Sterilization processes.

Substantial Equivalence:

The 3M Comply™ 1228 Gas Plasma Indicator Tape is comparable in performance to the Advanced Sterilization Products (ASP) STERRAD® Gas Plasma Indicator Tape (K945190). The 3M Comply 1228 Gas Plasma Indicator Tape and the predicate device share the same intended use to secure packs and as external pack indicators to differentiate processed from unprocessed items when exposed to vapor hydrogen peroxide in the STERRAD 100, STERRAD 100S, and the STERRAD 50 sterilization processes. In addition, the 3M Comply™ 1228 Gas Plasma Indicator Tape 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 3M Comply™ 1228 Gas Plasma Indicator Tape samples turned from blue to pink when exposed to the STERRAD 100 Sterilization cycle and the minimum time required for all indicator tape samples to indicate a "pass" in relation to the color match was found.
Cycle Conditions Required for Color Change Using the STERRAD 100S Cycle	Testing verified that the 3M Comply™ 1228 Gas Plasma Indicator Tape samples turned from blue to pink when exposed to the STERRAD 100S Sterilization cycle and the minimum time required for all indicator tape samples to indicate a "pass" in relation to the color match was found.
Cycle Conditions Required for Color Change in a STERRAD 50 Sterilizer	Testing verified that the 3M Comply™ 1228 Gas Plasma Indicator Tape samples turned from blue to pink when exposed to the STERRAD 50 Sterilization cycle and the minimum time required for all indicator tape samples to indicate a "pass" in relation to the color match was found.
Eighteen-Month Color Change Stability Study	Six-month interim results verified that all indicator tape turned from blue to pink when exposed to the complete STERRAD 100S Sterilization cycles, thereby confirming the continued stability of the 3M Comply™ 1228 Gas Plasma Chemical Indicator to date. Eighteen-Month color change stability testing is ongoing.
Eighteen-Month Adhesive Stability Study	Six-month interim results have found no initial trends in the peel force over time for both unprocessed tape and processed tape when removed from Kimberly-Clark Spungard One-Step wrap. Six-month interim results have verified wrap security. Eighteen-Month adhesive stability testing is ongoing.

Light Stability Testing

Testing verified that the colors of the processed and unprocessed 3M Comply™ 1228 Gas Plasma Indicator Tape samples did not change significantly after four (4) weeks of exposure to fluorescent light.

Performance After Exposure to Light

Testing verified that all indicator tape samples continued to meet the color match when exposed to both the complete STERRAD 100S Sterilization cycles, thereby confirming the stability of the 3M Comply™ 1228 Gas Plasma Indicator Tape samples following four (4) weeks of exposure to fluorescent light.

Effect of the Absence of Hydrogen Peroxide on the Color Change

Testing verified that the 3M Comply™ 1228 Gas Plasma Indicator Tape samples 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 3M Comply™ 1228 Gas Plasma Indicator Tape samples were found to be unaffected by the steam or ethylene oxide sterilization process. The Instructions For Use includes a Precaution not to use the indicator tape to monitor steam or ethylene oxide sterilization cycles.

Effects of Acid and Base

Testing verified that the 3M Comply™ 1228 Gas Plasma Indicator Tape samples were not sensitive to the presence of an acidic or basic (alkaline) environment. The unprocessed color of the 3M Comply 1228 Gas Plasma Indicator Tape samples was found to be sensitive to the presence of an acidic and basic (alkaline) environment, but does not change to pink, the processed color. The Instructions For Use includes a Precaution to store the indicator tape away from hydrogen peroxide and alkaline chemicals.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 2 2002

Ms. Joann L. Huehn
3M Company
Medical Division
3M Center, Building 275-5W-06
Saint Paul, Minnesota 55144-1000

Re: K020589
Trade/Device Name: 3M™ Comply™ 1228 Gas Plasma Indicator Tape
Regulation Number: 880.2800 (b)
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: February 21, 2002
Received: February 22, 2002

Dear Ms. Huehn:

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: TBD

Device Name: 3M™ Comply™ 1228 Gas Plasma Indicator Tape

Indications For Use: The 3M™ Comply™ 1228 Gas Plasma Indicator Tape is indicated for use to secure packs and as an external pack indicator to differentiate processed from unprocessed items when exposure to vapor hydrogen peroxide in the STERRAD® sterilization processes (100, 100S, 50). The 3M Comply 1228 is suitable for use on non-woven disposable wraps and peel pouches. The diagonal stripes of chemical indicator ink turn from blue to pink after exposure to vapor hydrogen peroxide in these sterilization processes.

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(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020589