JUL 10 1998

510(k) Summary of Safety and Effectiveness

K974415

Manufacturer:	Kimberly-Clark Corporation 1400 Holcomb Bridge Road Roswell, GA 30076
Regulatory Affairs Contact:	Larry R. Kludt Manager Regulatory Affairs Kimberly-Clark Corporation 1400 Holcomb Bridge Road Roswell, GA 30076 (770) 587-8279
Summary Date:	November 20, 1997
Product Trade Name:	Kimberly-Clark™ Gas Plasma Indicator Strip
Common Name:	Chemical Indicator
Classification:	Indicator, Chemical Indicator Strip
Predicate Device:	J & J STERRAD* Chemical Indicator Strip
Description:	The Kimberly-Clark Gas Plasma Indicator Strip (KCGPIS) is manufactured from a Tyvek® material or other synthetic substrate. The indicator is approximately ¾ " wide by 4 inches long and is flexographically printed with a hydrogen peroxide sensitive ink.
Intended Use:	The KCGPIS is a chemical sterilization process indicator as defined in 21 CFR Part 880.2800(b). The indicator strip is intended to be used by a health care provider to accompany products being sterilized via a low temperature, (STERRAD) sterilization process. The indicator strip is used to differentiate between product that has been exposed to hydrogen peroxide and product that has not been exposed to hydrogen peroxide. The strip will change color, from blue to green, upon exposure to the low temperature sterilant (hydrogen peroxide).
Technological Characteristics:	Both the STERRAD Chemical Indicator Strip and the Kimberly-Clark Gas Plasma Indicator Strip have a one year expiration date. Both products can be used to distinguish between products that have been exposed, or not exposed, to hydrogen peroxide sterilant, via a visible color change.

Summary of Testing

Test	Result
Aging Study	Aging (30 days @ 40° C/0% RH) did not affect the ability of the product to function as an indicator. Visual color comparisons confirmed that the control and aged samples had no significant difference in color.
Fading Properties	The KCGPIS exposed to fluorescent light, over 12 days of continuous exposure, showed less fading that the STERRAD strip. The KCGPIS maintained 80% of its color vs 37.4% color retention for the STERRAD strip.
pH Buffer and Chemical Testing	Both the KCGPIS and the STERRAD strip were tested pre and post sterilization. Both strips were sensitive to alkaline based materials but the KCGPIS provided better resistance to acidic materials than did the STERRAD strip. The KCGPIS experienced 7 of 33 color changing exposures while the STERRAD strip experienced color changes in 27 of 32 samples.
EO/Steam Sterilization	The purpose of this experiment was to validate the absence of color conversion of the KCGPIS by steam and EO sterilization. Both the KCGPIS and the STERRAD strips were tested in EO and steam sterilizers and both products maintained their pre-process colors.
Indicator Efficacy	Color change as a result of a completed STERRAD sterilization cycle revealed total color conversion, from blue to green, when contained in pouches and wrapped trays containing medical instruments. KCGPIS adequately tracked exposure to hydrogen peroxide sterilant and the color change (to green) was complete in all samples at the end of the diffusion cycle.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 10 1998

Kimberly-Clark Corporation
C/O Mr. Larry R. Kludt
Manager Regulatory Affaris
1400 Holcomb Bridge Road
Roswell, Georgia 30076

Re: K974415
Trade Name: Kimberly-Clark™ Gas Plasma Sterilization Indicator Strip
Regulatory Class: II
Product Code: JOJ
Dated: June 26, 1998
Received: June 29, 1998

Dear Mr. Kludt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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

510(k) Number (if known): K974415

Device Name: Kimberly-Clark Gas Plasma Indicator Strip

Indications For Use:

The Kimberly-Clark™ Gas Plasma Indicator Strip is a chemical sterilization process indicator as defined in 21 CFR Part 880.2800(b). The indicator strip is intended to be used by a health care provider to accompany products being sterilized via a low temperature (STERRAD) sterilization process. The indicator strip is used to differentiate between product that has been exposed to hydrogen peroxide and product that has not been exposed to hydrogen peroxide. The strip will change color, from blue to green, upon exposure to the low temperature sterilant (hydrogen peroxide).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Chin S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K974415

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)