

JUN 10 1999

510(k) SUMMARY
ALBERT BROWNE LTD.
BROWNE MVI ETHYLENE OXIDE INDICATOR

K 93 1418

1. **SUBMITTED BY**

Albert Browne Ltd.
Chancery House
190 Waterside Road
Hamilton Industrial Park
Leicester LE5 1QZ
United Kingdom

CONTACT PERSON

Alan Charlton
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Albert Browne Ltd.
190 Waterside Road
Hamilton Industrial Park
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DATE PREPARED

April 22, 1999

2. **DEVICE NAME**

Browne MVI Ethylene Oxide Indicator

CLASSIFICATION NAME

Physical/chemical sterilization process indicator

CLASSIFICATION STATUS

Physical/chemical process indicators are classified as Class II (Product Code 80JOJ) in 21 CFR 880.2800 by the General Hospital and Personal Use Devices Panel.

3. PREDICATE DEVICE

Gas-Chex® Sterilization Indicator Strips, Propper Mfg. Corp.

4. INTENDED USE

The Browne MVI Ethylene Oxide Indicator (Browne MVI EO Indicator) is a process indicator designed to indicate, through a visible color change, when the device has been exposed to an ethylene oxide sterilization process.

5. DEVICE DESCRIPTION

The Browne MVI EO Indicator is a paper strip with indicator ink pads on each end which is used to monitor ethylene oxide sterilization cycles. The indicator ink changes color from orange to red after exposure to an ethylene oxide sterilization process. After inclusion in an ethylene oxide sterilization cycle, the color of the indicator ink pads is compared to a reference spot which matches the red color of the exposed strip.

6. TECHNOLOGICAL CHARACTERISTICS

The color change in both the proposed and predicate devices is produced by interaction of the active ingredient with ethylene oxide which induces a change in the color of a pH indicator dye.

7. PERFORMANCE TESTING

The Browne MVI EO Indicator conforms to the applicable requirements of ANSI/AAMI ST60-1996 "Sterilization of health care products - Chemical indicators - Part 1: General requirements". Data was also included to support a 2 year shelf life for the device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 10 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Albert Browne Limited
c/o Cynthia J.M. Nolte, Ph.D., RAC
Associate Consultant
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K991418
Trade Name: Browne MVI Ethylene Oxide Indicator
Regulatory Class: II
Product Code: JOJ
Dated: April 22, 1999
Received: April 23, 1999

Dear Dr. Nolte:

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 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 (Pre-market 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

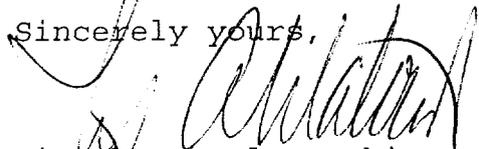
Page 2 - Dr. Nolte

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" (21 CFR 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) 638-2044 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/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): _____

Device Name: Browne MVI Ethylene Oxide Indicator

Indications For Use:

The Browne MVI Ethylene Oxide Indicator is a process indicator designed to indicate, through a visible color change, when the device has been exposed to an ethylene oxide sterilization process.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K991418

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number _____
[Signature]

Prescription Use _____ OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)