

JAN 29 1998

**510(k) Summary
Albert Browne Ltd.
Browne MVI Steam Indicator**

K971369

1. SUBMITTED BY

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

CONTACT PERSON

Alan Charlton
Chancery House
190 Waterside Road
Hamilton Industrial Park
Leicester LE5 1QZ

DATE PREPARED

December 16, 1997

2. DEVICE NAME

Browne MVI Steam Indicator

CLASSIFICATION NAME

Physical/chemical sterilization process indicator

CLASSIFICATION STATUS

Physical/chemical process indicator is classified as Class II under Sterilization process indicator in 21 CFR 880.2800 by the General Hospital and Personal Use Devices Panel.

3. PREDICATE DEVICE

Strate-Line™ Sterilization Indicator Strip, Propper Manufacturing Co., Inc.

4. INTENDED USE

The Browne MVI Steam Indicator is a sterilization process indicator designed to indicate, through a visible color change, when the device has been exposed to a steam sterilization process.

5. DEVICE DESCRIPTION

The Browne Steam Indicator is a paper strip with indicator ink pads on each end which is used to monitor steam sterilization cycles. The indicator ink changes color from white to purple through a pink intermediate in a steam autoclave working at 121-134°C.

6. TECHNOLOGICAL CHARACTERISTICS

The Browne MVI Steam Indicator consists of a paper strip with chemical indicator ink pads located on each end. The device is designed to monitor steam sterilization processes in gravity and vacuum-assisted steam autoclaves with a working range of 121-134°C. The color change in both devices is produced by a temperature-dependent chemical reaction.

7. PERFORMANCE TESTING

All performance testing was conducted in a BIER vessel/prototype which conforms to the performance requirements for BIER/Steam vessels described in ANSI/AAMI ST45-1992.

Testing was conducted to evaluate the performance of the strips in partial cycles at 121°C and 134°C. The data showed that the strips changed color from white to purple with a pink intermediate. The time required for complete development of an end point response was ≥ 7 minutes at 121°C and ≥ 3 minutes at 134°C. The data demonstrates that the device can be used for the confirmation of exposure to a steam sterilization process in a steam autoclave with a working range of 121-134°C.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 29 1998

Albert Browne Ltd.
C/O Ms. Mary McNamara-Cullinane
Staff Consultant
Medical Device Consultants
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K971369
Trade Name: Browne MVI Steam Chemical Indicator
Regulatory Class: II
Product Code: JOJ
Dated: December 17, 1997
Received: December 18, 1997

Dear Ms. McNamara-Cullinane:

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.

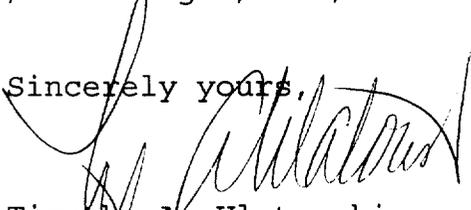
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, 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) 594-4618. 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" (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) 638-2041 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 Steam ^{Chemical} Indicator

Indications For Use:

The Browne MVI Steam Indicator is a process indicator designed to indicate, through a white to purple color change, when the device has been exposed to a steam sterilization process in a working range of 121-134°C.

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

Chin S. Kim

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K971369

Prescription Use _____

OR

Over-The-Counter Use X

(Per 21 CFR 801.109)