JUN 24 1997

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

K970918

1. SUBMITTED BY

Albert Browne Ltd.
Chancery House
Rosebery Road
Anstey
Leicester LE7 7EL
United Kingdom

CONTACT PERSON

Alan Charlton
Chancery House
Rosebery Road
Anstey
Leicester LE7 7EL
United Kingdom

DATE PREPARED

March 11, 1997

2. DEVICE NAME

Browne 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

3M Comply 1250 Steam Integrator Strips, 3M Health Care.

4. INTENDED USE

The Browne Steam Indicator is a process indicator to be used in a steam autoclave with a working range of 121-134°C to distinguish between processed and unprocessed units.

5. DEVICE DESCRIPTION

The Browne Steam Indicator is a paper strip with indicator ink pads on each end. The indicator ink pads change color from white to black through a brown intermediate in a steam autoclave working at 121-134°C (250-273°F).

6. TECHNOLOGICAL CHARACTERISTICS

The Browne Steam Indicator consists of a paper strip with chemical indicator ink pads located on each end. The device is designed to be used 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 black with a brown intermediate. The time required for complete development of an end point response was ≥8 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 processing cycle in a steam autoclave with a working range of 121-134°C. The performance of the Browne Steam Indicator was equivalent to that of the predicate device.

All strips used for testing were ≥2 years from the date of manufacture, demonstrating that the 2-year expiration date is adequate to ensure accurate, reproducible performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES · Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 1997

Cynthia J.M. Nolte, Ph.D.
Associate Consultant
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760-4153

Re: K970918
Trade Name: Browne Steam Indicator
Regulatory Class: II
Product Code: JOJ
Dated: May 1, 1997
Received: May 2, 1997

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 (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 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. 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 at (301) 443-6597.

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): K970918

Device Name: Browne Steam Indicator

Indications For Use:

The Browne Steam Indicator is a process indicator to be used in a steam autoclave with a working range of 121-134°C to distinguish between processed and unprocessed units.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K970918

Prescription Use _____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)