JAN 1 0 2000

ABBREVIATED 510(K) SUMMARY
ALBERT BROWNE LTD.
BROWNE PACKAGING AND LABEL STEAM PROCESS INDICATOR

K992767

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

CONTACT PERSON: Alan Charlton
Chancery House
190 Waterside Road
Hamilton Industrial Park
Leicester LE5 1QZ
United Kingdom

Date Prepared: November 8, 1999

2. **DEVICE NAME:** Browne Packaging and Label Steam Process Indicator

Classification Name: Physical/chemical sterilization process indicator

Classification Status: Physical/chemical process indicators are 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 Autoclave Tape, 3M Health Care (K932129)

4. INTENDED USE

The Browne Packaging and Label Steam Process Indicator (Packaging and Label Steam Indicator) is a process indicator which undergoes a visual color change when exposed to steam in a temperature range of 121°C to 134°C (250°F to 273°F).

5. DEVICE DESCRIPTION

The Packaging and Label Steam Indicator is a chemical indicator consisting of indicator ink applied to a suitable substrate. The indicator ink changes color from pink to purple in a steam autoclave in a temperature range of 121°C to 134°C (250°F to 273°F).

The purpose of this submission is to:

- Replace the process indicator on the outer wrapper of the Browne TST Single Use Bowie Dick Type Test Pack (Browne Bowie Dick Test Pack, K971971) with the Packaging and Label Steam Indicator;

- Market the Packaging and Label Steam Indicator, consisting of indicator ink printed onto clay-coated label stock with permanent or peelable adhesive and a siliconized backing.

6. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the Packaging and Label Steam Indicator and the 3M Autoclave Tape are similar. The proposed and predicate devices consist of indicator ink applied to a substrate. The indicator ink changes color to confirm exposure to steam. The proposed device changes color from pink to purple and the predicate device changes color from off white to brown.

The predicate device is composed of indicator ink applied to a paper substrate. The Packaging and Label Steam Indicator consists of indicator ink applied using a printing method to steam sterilizable paper or clay-coated label stock.

7. PERFORMANCE TESTING

Albert Browne Ltd. has performed testing which demonstrates that the Browne Packaging and Label Steam Indicator conform to the applicable requirements of ANSI/AAMI ST60 for Class I process indicators for steam sterilization. Additional testing showed that the indicator changed color after approximately 2.5 minutes exposure to a 132°C autoclave processing cycle. Data was provided to support a two-year shelf life.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 0 2000

Cynthia J.M. Nolte, Ph.D., RAC
Staff Consultant
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, MA 02760

Re: K992767
Trade Name: Browne Packaging and Label Steam Process Indicator
Class: II
Product Code: JOJ
Dated: November 8, 1999
Received: November 9, 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 (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) 594-4692. 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) 638-2041 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): K992767

Device Name: Browne Packaging and Label Steam Process Indicator

Indications for Use:

The Browne Packaging and Label Steam Process Indicator is a process indicator which undergoes a visual color change when exposed to steam in a temperature range of 121°C to 134°C (250°F to 273°F).

(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 K992767

Prescription Use _____ OR Over-The-Counter Use X

(Per 21 CFR 801.109)