

## 510(k) Summary

AUG 25 2006

### Albert Browne Ltd. VERIFY® STEAM and EO Load Record Card

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

**CONTACT PERSON:** Richard Bancroft  
Chancery House  
190 Waterside Road  
Hamilton Industrial Park  
Leicester LE5 1QZ  
United Kingdom

Telephone: 0116 276 8636

**DATE PREPARED:** August 10, 2006

2. **DEVICE NAME:** VERIFY® STEAM and EO Load Record Card  
**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 (Product Code JOJ) by the General Hospital and Personal Use Devices Panel

3. **PREDICATE DEVICES**

- Browne MVI Ethylene Oxide Indicator (K991418)
- Albert Browne, Ltd. VERIFY® STEAM Value Indicators (K060103)
- Steam/EO Record Card (K000502)

**4. INTENDED USE**

The Albert Browne Ltd. VERIFY® STEAM and EO Load Record Card contains process indicators that undergo a visual color change when exposed to steam in a temperature range of 121°C to 135°C (250°F to 275°F) or an ethylene oxide sterilization process.

**5. DEVICE DESCRIPTION**

The proposed VERIFY® STEAM and EO Load Record Card is a 5"x3" card containing space for recording information regarding the load to be processed and two indicator ink strips applied to the card using a rotary screen printing method. The indicator ink strips are steam and ethylene oxide-sensitive indicators that change color following exposure to the appropriate sterilant.

**6. TECHNOLOGICAL CHARACTERISTICS**

The indicator inks and substrate used for the manufacture of the proposed VERIFY® STEAM and EO Load Record Card are identical to those described in K991418 and K060103 for the Browne MVI Ethylene Oxide Indicator and Albert Browne, Ltd. VERIFY® STEAM Value Indicators, respectively. The printing process used for application of the indicator inks to the substrate is also identical for the proposed and predicate devices. A tabular comparison of the proposed and predicate devices is provided on the following page.

**7. PERFORMANCE TESTING**

Testing was provided in K991418 and K060103 to validate the indicator ink-substrate combinations for use in confirming exposure to ethylene oxide and steam sterilization processes, respectively. Albert Browne Ltd. has performed testing which demonstrates that the indicators perform as intended under in use conditions.

## Comparison Chart for Determination of Substantial Equivalence

| Technological Characteristics | VERIFY®<br>STEAM and EO Load Card<br>(proposed)  | Browne<br>MVI Ethylene Oxide Indicator<br>(K991418)   | VERIFY®<br>STEAM Value Indicators<br>(K060103)   | SteriTec Products, Inc.<br>Steam/EO Record Card<br>(K000502)   |
|-------------------------------|--|---|--|--|
| Intended Use                  | Confirm exposure to a sterilant through a visible color change   |   |  |  |
| Sterilization Processes       | <ul style="list-style-type: none"> <li>• Steam</li> <li>• EO</li> </ul>  | EO  | Steam  | <ul style="list-style-type: none"> <li>• Steam</li> <li>• EO</li> </ul>  |
| Color change                  | <ul style="list-style-type: none"> <li>• Blue to black (steam)</li> <li>• Orange to red (EO)</li> </ul>                                      | Orange to red   | Blue to black  | <ul style="list-style-type: none"> <li>• Blue to black (steam)</li> <li>• Yellow to brown (EO)</li> </ul>              |
| Materials of Construction     | <ul style="list-style-type: none"> <li>• Steam and EO-sensitive indicator inks<sup>1</sup></li> <li>• paper substrate<sup>2</sup></li> </ul> | <ul style="list-style-type: none"> <li>• EO-sensitive indicator ink</li> <li>• paper substrate</li> </ul> | <ul style="list-style-type: none"> <li>• Steam-sensitive indicator ink</li> <li>• paper substrate</li> </ul> | <ul style="list-style-type: none"> <li>• Steam and EO-sensitive indicator inks</li> <li>• Unknown substrate</li> </ul> |
| Disposable                    | Yes  | Yes   | Yes  | Yes  |
| Sterile                       | No   | No  | No   | No   |

EO = Ethylene oxide

<sup>1</sup>The steam and EO-sensitive indicator inks are identical to the inks described and tested in K060103 and K991418.

<sup>2</sup>The substrate used in the proposed device is identical to the VERIFY® STEAM Value Indicators and MVI Ethylene Oxide Indicator



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Albert Browne Limited  
C/O Dr. Cynthia J. M. Nolte  
Senior Staff Consultant  
Medical Device Consultants, Incorporated  
49 Plain Street  
North Attleboro, Massachusetts 02760

**AUG 25 2006**

Re: K061738  
Trade/Device Name: Albert Browne Ltd. VERIFY STEAM and EO Load Record Card  
Regulation Number: 880.2800  
Regulation Name: Sterilization Process Indication  
Regulatory Class: II  
Product Code: JOJ  
Dated: August 10, 2006  
Received: August 11, 2006

Dear Dr. Nolte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

