

K 971971  
July 10, 1998

**510(k) SUMMARY**  
**Browne TST Single Use Bowie-Dick Type Test Pack**  
**April 3, 1998**

**1. SUBMITTER NAME AND ADDRESS**

Mr. Alan Charlton  
Albert Browne Ltd.  
190 Waterside Road  
Hamilton Industrial Park  
Leicester LE5 1QZ  
United Kingdom

**2. DEVICE NAME**

Proprietary Name: Browne TST Single Use Bowie-Dick Type Test Pack  
Common/Usual Name: Bowie-Dick Test  
Classification Name: Physical/Chemical Process Indicator

**3. PREDICATE DEVICE**

Browne TST Single Use Bowie-Dick Type Test Pack, subject of K932057

**4. INTENDED USE**

The Browne TST Single Use Bowie-Dick Type Test Pack is a chemical sterilization process monitor which demonstrates adequate air removal and steam penetration during a 132°C (270°F) or 134°C (273°F) autoclave processing cycle by means of a yellow to blue color change.

**5. DEVICE DESCRIPTION**

The Browne TST Single Use Bowie Dick Type Test Pack is a paper sheet containing an indicator figure wrapped in multiple layers of paper which is designed to monitor air removal and steam penetration during a 132°C (270°F) or 134°C (273°F) steam autoclave processing cycle with a hold time of 3-4 minutes. The device changes color from yellow to blue when air removal during the cycle is sufficient to allow complete, even, steam penetration.

## 6. TECHNOLOGICAL CHARACTERISTICS

The device is composed of an indicator sheet, containing the indicator ink figure.

The indicator sheet is wrapped in layers of paper which serves as a barrier to steam penetration. The chemical composition of the ink controls the temperature required for a color change to occur in the presence of complete, even steam penetration. A circular process indicator is affixed to the test pack label which changes color from yellow to blue when exposed to steam.

## 7. PERFORMANCE TESTING

Performance testing has been conducted which showed that the sensitivity of the Test Packs is sufficient to detect a  $\geq 2^{\circ}\text{C}$  temperature depression at  $132^{\circ}\text{C}$  ( $270^{\circ}\text{F}$ ) or  $134^{\circ}\text{C}$  ( $273^{\circ}\text{F}$ ) in a test cycle of 3-4 minutes duration. The data supports the use of the Test Pack to monitor air removal during a steam autoclave processing cycle. Additional testing conducted in a loaded chamber demonstrated that the sensitivity of the Test Pack was not affected by the presence of the load.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 10 1998

Albert Browne Ltd.  
C/O Cynthia J.M. Nolte, Ph.D.  
Associate Consultant  
Medical Device Consultants, Incorporated  
49 Plain Street  
North Attleboro, Massachusetts 02760

Re: K971971  
Trade Name: Browne TST Single Use Bowie-Dick Type Test  
Pack  
Regulatory Class: II  
Product Code: JOJ  
Dated: June 8, 1998  
Received: June 9, 1998

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 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). 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 Current Good Manufacturing Practice requirements, 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

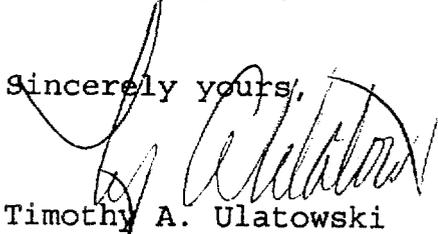
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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" (21CFR 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/dsma/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

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510(k) Number (if known): K971971

Device Name: Browne TST Single Use Bowie-Dick Type Test Pack

Indications For Use:

The Browne TST Single Use Bowie-Dick Type Test Pack is a chemical sterilization process monitor which demonstrates adequate air removal and steam penetration during a 132°C (270°F) or 134°C (273°F) autoclave processing cycle by means of a yellow to blue color change.

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number K971971

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

Browne TST Single Use Bowie-Dick Type Test  
Additional Information - K971971

CONFIDENTIAL

4/3/98

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