K965154
Sept 19, 1997

510(k) SUMMARY
Albert Browne Ltd.
TST Control Integrator for Steam Autoclave

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

April 24, 1997

2. DEVICE NAME

TST Control Integrator for Steam Autoclave

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 DEVICES

TST Control Integrator for Steam Autoclave, Albert Browne Ltd.

4. INTENDED USE

The TST Control Integrator for Steam Autoclave is a steam sterilization process indicator designed to indicate, through a yellow to blue color change, when a combination of parameters necessary for sterilization (270°F for 3 minutes) have been achieved.

5. DEVICE DESCRIPTION

Albert Browne Ltd. received clearance for a TST Control Integrator for Steam Autoclave, K902958, which monitored sterilization cycles with a holding temperature/time combinations of 250°F (121°C)/15 min. The purpose of this submission is to expand the process parameter combinations to include a cycle of 270°F/3 min.

Like the integrator described in K902958, the TST steam integrator discussed in this amendment changes color from yellow to blue when a specific set of process parameters required for steam sterilization to occur have been met. The parameters of the sterilization cycle monitored by the proposed integrator - time, temperature and the presence of steam - are equivalent to those monitored by the integrators described in K902958. Albert Browne Ltd. is amending K902958 in order to increase the combinations of parameters which produce a color change to include additional temperatures. The time-temperature combinations in sterilization cycles which will induce TST Control Integrators to change color from yellow to blue are presented in Table 1.

Table 1. Performance Characteristics for the TST Control Integrator for Steam Autoclave

Temperature	Time (minutes)	Presence of Steam	Regulatory Status
250°F	15	yes	K902958
270°F	3	yes	proposed

6. TECHNOLOGICAL CHARACTERISTICS

The TST steam integrator consists of a paper strip with the chemical indicator ink located on one end. The color change is pH based. The time and temperature required for the color change to occur is precisely controlled through manipulation of the chemical composition of the ink.

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 and full cycles. The data showed that the strips changed color only when exposed to saturated steam for 3 minutes at 270°F, confirming that the integrators will accurately report exposure to those conditions.

Side by side testing was performed with biological indicators. The results showed that the temperature/time required for color change to occur provides wide safety margin over that necessary to kill the spores on a biological indicator, indicating that the conditions required for a color change to occur are sufficient for sterilization.

Additional testing was performed which demonstrated that the color change was stable at least 5 years after exposure. All strips used for testing were all ≥3 years from the date of manufacture, demonstrating that the 3 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

SEP 19 1997

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

Re: K965154
Trade Name: TST Control Integrator For Steam Autoclave
Regulatory Class: II
Product Code: JOJ
Dated: June 25, 1997
Received: June 26, 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 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): K965154

Device Name: TST Control Integrator for Steam Autoclave

Indications For Use:

The TST Control Integrator for Steam Autoclave is a steam sterilization process indicator designed to indicate, through a yellow to blue color change, when a combination of parameters (270°F, 3 min.) necessary for sterilization have been achieved.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Chin S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K965154

Prescription Use _____
(Per 21 CFR 801.109)

OR Over-The-Counter Use X

(Optional Format 1-2-96)