

FEB 4 1999

K984613

510(k) SUMMARY
BROWNE SPORICIDIN PHENOL INDICATOR FOR
SPORICIDIN STERILIZING AND DISINFECTING SOLUTION

1. SUBMITTER NAME AND ADDRESS

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

2. DEVICE NAME

Proprietary Name: Browne Sporicidin Phenol Indicator for Sporicidin
Sterilizing and Disinfecting Solution
Common/Usual Name: Browne Sporicidin Phenol Indicator
Classification Name: Physical/Chemical Sterilization Process Indicator

3. PREDICATE DEVICES

Browne GA Indicator (K922481)

4. INTENDED USE

The Browne Sporicidin Phenol Indicator for Sporicidin Sterilizing and Disinfecting Solution (Browne Sporicidin Phenol Indicator) is a phenol concentration monitor for use in phenol-containing germicides with a minimum effective concentration (MEC) of 1.3% phenol.

The Browne Sporicidin Phenol Indicator is dedicated for use with Sporicidin Sterilizing and Disinfecting Solution.

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5. DEVICE DESCRIPTION

The Browne Sporicidin Phenol Indicator and the substantially equivalent device are chemical indicator strips intended to monitor the concentration of the active ingredient of a liquid chemical germicide. The devices indicate, via a color change, if the concentration of the active ingredient exceeds the MEC for the solution.

The Browne Sporicidin Phenol Indicator consists of a polypropylene strip with an indicator pad on one end. The indicator pad is impregnated with an indicator solution which changes color from yellow to green in liquid chemical germicides with a phenol concentration above the MEC of 1.3%.

The Browne Sporicidin Phenol Indicator and the predicate device have a 2-year shelf life from the date of manufacture in the unopened bottle. Containers of both devices have a 90 day in-use life.

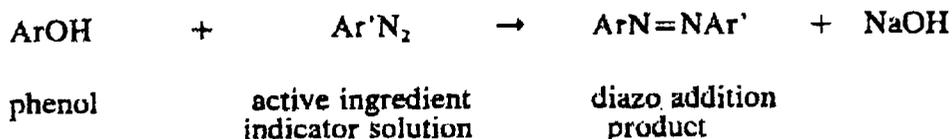
6. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the Browne GA Indicator are similar to that of the Browne Sporicidin Phenol Indicator described in this submission. Both devices are non-sterile, disposable strips containing an indicator pad impregnated with an indicator solution which changes color in a germicide solution at the appropriate concentration of the active ingredient of the liquid chemical germicide.

The mechanism of action for inducing a color change is identical for the Browne Sporicidin Phenol Indicator and the Browne GA Indicator. The active ingredient of the indicator solution in both devices interacts with the active ingredient in the germicide solution to produce a hydroxyl ion which ionizes a pH-sensitive dye.

In the proposed device, the phenol component of the Sporicidin Sterilizing and Disinfecting Solution reacts with the active ingredient in the indicator solution of the test strip to form a diazo addition product (STEP 1). If sufficient phenol is present, the increase in pH causes a color change in the pH indicator dye (STEP 2).

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STEP 1**STEP 2**

The indicator color is dependent on the phenol concentration of the germicide solution, and the time after exposure when the results of the test are read, as described in the Table A-1 below.

Table A-1. Color Development for the Sporicidin Phenol Indicator Strip

Time (minutes)	Phenol Concentration (%)		
	≤1.3	1.4-1.5	≥1.6
<1	yellow, green/yellow		
1-2	yellow	yellow, green/yellow, green	green
>2	yellow, green/yellow		

During the first 60 seconds after the test strip has been dipped into the Sporicidin Sterilizing and Disinfecting Solution, the yellow test strip will begin to develop a green color.

At 60 seconds (1 minute), the strip will exhibit a uniform green color (except for the top 2 mm of the strip) if the concentration of phenol in the Sporicidin Sterilizing and Disinfecting Solution is ≥1.6%. The strip will appear patchy green/yellow or yellow if the solution contains ≤1.3% phenol. In the concentration range of 1.4-1.5% phenol, the strip may appear yellow, green/yellow or green.

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From 60 to 120 Seconds (1 to 2 minutes) the color of the strip is stable. A color reading must be taken during this time period for the results to accurately reflect the phenol concentration of the Sporicidin Sterilizing and Disinfecting Solution.

After 120 seconds (2 minutes) the color of the strip regresses toward the original yellow color. The rate of regression is dependent on the phenol concentration of the Sporicidin Sterilizing and Disinfecting Solution.

The indicator solution of the proposed device changes color from yellow to green to indicate a PASS, while that of the Browne GA Indicator changes color from yellow to purple to indicate a PASS. The difference in colors chosen for these indicators does not represent a difference in the mechanism of action for the production of a color change.

7. PERFORMANCE TESTING

The performance characteristics of the Browne Sporicidin Phenol Indicator were established by testing indicators in Sporicidin Sterilizing and Disinfecting Solution containing 1.6% and 1.3% phenol. The test indicators showed a 100% failure rate in the 1.3% solution when the testing was performed according to the Instructions for Use. Some false negatives were observed. The frequency of false negatives increased when the indicators were tested in the presence of high levels of detergent and salt contaminants, or when testing was performed by inexperienced users.

No false positives were recorded in any of the testing conducted. The false negatives reported would have caused the user to discard the solution unnecessarily. No disinfection procedure would have been compromised.

The data demonstrates that the Browne Sporicidin Phenol Indicator is an effective monitor for the phenol component of the Sporicidin Sterilizing and Disinfecting Solution with a phenol MEC of 1.3%.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 4 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K984613
Trade Name: Browne Sporocidin Phenol Indicator
for Sporocidin Sterilizing and Disinfecting Solution
Regulatory Class: II
Product Code: JOJ
Dated: December 28, 1998
Received: December 29, 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 (Pre-market 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 pre-market notification submission does not affect any obligation you might have under sections 531

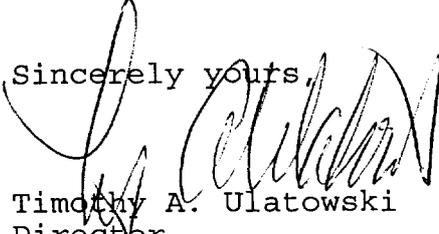
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

510(k) Number (if known): K984613

Device Name: Browne Sporicidin Phenol Indicator For Sporicidin Sterilizing and Disinfecting Solution

Indications For Use:

The Browne Sporicidin Phenol Indicator For Sporicidin Sterilizing and Disinfecting Solution (Browne Sporicidin Phenol Indicator) is a phenol concentration monitor for use in phenol-containing germicide solutions with a minimum effective concentration of 1.3% phenol.

The Browne Sporicidin Phenol Indicator is dedicated for use with Sporicidin Sterilizing and Disinfecting Solution.

(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 K984613

Prescription Use _____
(Per 21 CFR 801.109)

OR Over-The-Counter Use X