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OCT 8 1999

**510(k) SUMMARY
Browne Cidex™ OPA Indicator
August 4, 1999**

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 Cidex™ OPA Indicator
Common/Usual Name: ortho-Phthalaldehyde Concentration Indicator
Classification Name: Physical/Chemical Sterilization Process Indicator

3. PREDICATE DEVICES

Browne GA Indicator, subject of K922481

4. INTENDED USE

The Browne Cidex™ OPA Indicator (Browne OPA Indicator) is a concentration monitor for use in ortho-phthalaldehyde-containing germicide solutions with a minimum effective concentration of 0.3%.

The Browne Cidex™ OPA Indicator is dedicated for use with Cidex™ OPA Solution.

5. DEVICE DESCRIPTION

The Browne OPA Indicator and the substantially equivalent device are chemical indicator strips intended to monitor the concentration of liquid chemical germicides. The devices indicate, via a color change, if the concentration of the

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active ingredient exceeds the MEC (minimum effective concentration) for the solution.

The Browne OPA 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 light blue to purple in Cidex™ OPA Solution with an ortho-phthalaldehyde concentration greater than the MEC for the solution.

6. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the Browne GA Indicator, subject of K922481, are equivalent to that of the Browne OPA 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 liquid chemical germicide at the appropriate concentration of the active ingredient.

The mechanism of action for the color change is identical for the proposed and predicate devices. The active ingredient of the indicator solution in both devices interacts with the aldehyde moiety of the active ingredient of the germicide solution to produce a color change at the appropriate concentration of the germicide active ingredient. The indicator solution of the proposed device changes color from light blue to purple, while that of the Browne GA Indicator, subject of K922481, changes color from yellow to purple.

7. PERFORMANCE TESTING

Performance testing was conducted on 180 Browne OPA Indicators from 3 production lots in Cidex™ OPA solutions containing 0.3% and 0.45% ortho-phthalaldehyde. Testing was performed according to the Instructions for Use. All 90 strips tested in the 0.3% solution were a light blue or light blue with purple mottling color, indicating a FAIL. All 90 strips tested in the 0.45% solution were a purple color, indicating a PASS.

Additional testing was conducted to evaluate the performance of the Browne OPA Indicator in Cidex™ OPA Solutions containing 0.3% or 0.45% ortho-phthalaldehyde using three production lots of strips under conditions of simulated

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use. All 30 of the indicators tested in the 0.3% ortho-phthalaldehyde solution showed a FAIL condition. All 30 of the indicators tested in the 0.45% solutions showed a PASS condition. No false positives or false negatives were recorded.

The performance of the Browne OPA Indicator was also evaluated under conditions selected to simulate a worst case condition for the germicide solution. The indicators were tested in Cidex™ OPA solution containing 0.3% and 0.45% ortho-phthalaldehyde at the end of its use life and contaminated with 5% serum, 5% salt, and 5% sodium dodecyl sulfate. An unadulterated solution was included as a control. For each of the contaminants tested, all of the indicator strips exhibited a FAIL condition in the 0.3% Cidex™ OPA solution and a PASS in the 0.45% solution.

The data shows that the Browne OPA Indicator is an effective monitor for the 0.3% MEC Cidex™ OPA Solution.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 8 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Albert Browne Ltd.
c/o Cynthia J.M. Nolte, Ph.D., RAC
Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K991709

Trade Name: Browne Cidex® OPA Indicator
Regulatory Class: II
Product Code: JOJ
Dated: September 15, 1999
Received: September 16, 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.

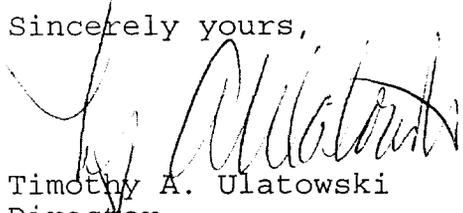
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the 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): K991709

Device Name: Browne Cidex™ OPA Indicator

Indications For Use:

The Browne Cidex™ OPA Indicator is a concentration monitor for use in ortho-phthalaldehyde-containing germicide solutions with a minimum effective concentration of 0.3%.

The Browne Cidex™ OPA Indicator is dedicated for use with Cidex™ OPA Solution.

(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

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Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X