DEC 7 1998

510(k) SUMMARY
Browne GA Indicator for Cidex Plus™ 28 Day Solution
October 8, 1998

K981054

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 GA Indicator for Cidex Plus™ 28 Day Solution
Common/Usual Name:	Glutaraldehyde Concentration Indicator
Classification Name:	Physical/Chemical Sterilization Process Indicator

3. PREDICATE DEVICES

Browne GA Indicator, subject of K922481
Cold Sterilog Glutaraldehyde Monitor, subject of K924681

4. INTENDED USE

The Browne GA Indicator for Cidex Plus™ 28 Day Solution (Browne Cidex Indicator) is a concentration monitor for use in glutaraldehyde-containing germicide solutions with a minimum effective concentration of 2.1%.

The Browne GA Indicator for Cidex Plus™ 28 Day Solution is dedicated for use only with Cidex Plus™ 28 Day Solution.

5. DEVICE DESCRIPTION

The Browne Cidex Indicator and the substantially equivalent devices are chemical indicator strips intended to monitor the concentration of glutaraldehyde solutions. The devices indicate, via a color change, if the glutaraldehyde concentration exceeds the MEC of the specific germicide solution they were designed to monitor.

6. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the Cold Sterilog Glutaraldehyde Monitor and Browne GA Indicator are similar to that of the Browne Cidex Indicator described in this submission. All three devices are non-sterile, disposable strips containing an indicator pad impregnated with an indicator solution which changes color at a glutaraldehyde concentration above the MEC of the liquid chemical germicide it is designed to monitor.

The mechanism of action for inducing a color change are identical for the Browne Cidex Indicator and the Browne GA Indicator, subject of K922481. Glutaraldehyde reacts with sodium sulfite in the test strip to form a sulfite addition product and an equivalent amount of base (STEP 1). If sufficient glutaraldehyde is present, the increase in pH causes a colour change in the pH indicator (STEP 2).

STEP 1

$HCO(CH_2)_3CHO$ + $2Na_2SO_3$ + $2H_2O$
glutaraldehyde sodium sulfite water

→ $(CH_2)_3(CH(SO_3Na)OH)_2$ + 2NaOH
sulfite addition product sodium hydroxide

STEP 2

NaOH + pH sensitive dye → red color dye

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

Table 1. Color Development for the Cidex Plus™ 28 Day Solution Indicator

Time (minutes)	Glutaraldehyde Concentration (%)		
	≤2.1	2.2-2.3	≥2.4
<1	Yellow, Red/Yellow		
1-2	Yellow, Red/Yellow	Yellow, Red/Yellow, Red	Red
>2	Yellow, Red/Yellow		

During the first 60 seconds after the test strip has been dipped into the Cidex Plus™ 28 Day Solution, following the procedure described in the Instructions for Use, the yellow test strip will begin to develop a red color.

At 60 seconds (1 minute), the strip will exhibit a uniform red color (except for the top 2 mm of the strip) if the concentration of glutaraldehyde is ≥2.4%. The strip will appear patchy red/yellow or yellow if the solution contains ≤2.1% glutaraldehyde. In the range of 2.2-2.3% glutaraldehyde, the strip may appear yellow, red/yellow or red.

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.

After 120 seconds (2 minutes) the color of the strip regresses toward the original yellow color. The rate of regression is dependent on the glutaraldehyde concentration of the Cidex Plus™ 28 Day Solution being tested.

The indicator solution of the proposed device changes color from yellow to red to indicate a PASS, while that of the Browne GA Indicator, subject of K922481, changes color from yellow to purple to indicate a PASS. The choice of colors for these indicators does not represent a difference in the mechanism of action for the color change.

7. PERFORMANCE TESTING

The performance characteristics of Cidex Plus™ 28 Day Solution Test Strips were established by testing 5 manufacturing lots of test strips in Cidex Plus™ 28 Day Solution with 2.1% and 2.4% glutaraldehyde. The test strip shows a 100% failure rate in solutions containing 2.1% glutaraldehyde when the testing was performed according to the Instructions for Use. The performance of the Cidex Plus™ 28 Day Solution Test Strips is not affected by the presence of detergent, organic and inorganic contaminants over the 28 day reuse period.

Testing was also conducted to evaluate the performance of the Browne Cidex Indicator in Cidex Plus™ 28 Day Solutions containing 2.1 or 2.4% glutaraldehyde under conditions of simulated use. Ten individuals who had not used the test strip previously were instructed to test the strips, following the Instructions for Use. All 20 of the indicators tested in the 2.1% solution showed a FAIL condition. Seventeen of the 20 indicators tested in the 2.4% solutions showed a PASS condition. Three of the 20 indicators tested in the 2.4% solution were incorrectly reported as failures. These false negatives were attributed to user inexperience.

No false positives were recorded, indicating that the Browne Cidex Indicator can accurately identify Cidex 28 Day Plus™ Solutions which are at or below the MEC of 2.1%. The false negatives would have caused the user to discard the solution unnecessarily. No disinfection procedure would have been compromised.

The data shows that the Browne Cidex Indicator is an effective monitor for the 2.1% MEC Cidex 28 Day Plus™ Solution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 7 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: K981054
Trade Name: Browne GA Indicator for Cidex Plus™ 28 Day Solution
Regulatory Class: II
Product Code: JOJ
Dated: October 8, 1998
Received: October 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

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): K981054

Device Name: Browne GA Indicator for Cidex Plus™ 28 Day Solution

Indications For Use:

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The Browne GA Indicator for Cidex Plus™ 28 Day Solution is dedicated for use with Cidex Plus™ 28 Day 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
510(k) Number K981054

Prescription Use _____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)