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Serim™
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510(k) SUMMARY

CIDEX®[1] OPA Solution Test Strips

SUBMITTED BY

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Date Prepared:	July 7, 1999

DEVICE NAME

Trade Name:	CIDEX® OPA Solution Test Strips
Common Name:	Test Strips for *ortho*-Phthalaldehyde (OPA) in CIDEX® OPA Solution
Classification Name:	Chemical Sterilization Process Indicator

PREDICATE DEVICE

Cidex® Solution Test Strips (K915170)

DESCRIPTION OF THE CIDEX® OPA SOLUTION TEST STRIP

The CIDEX® OPA Solution Test Strips consist of a 0.2 x 0.2-inch reagent-containing pad attached to one end of a 0.2 x 3.25-inch polystyrene handle. The indicator pad contains a color-forming reagent. It also contains an inhibiting compound that prevents visible reaction when the OPA concentration is at or below the MEC. When the OPA level is in sufficient excess of the MEC, the surplus reacts with the color-forming reagent.

The sample is placed in a 12 x 75-mm glass test tube. The indicator pad is immersed in the sample for 30 seconds, removed and allowed to react for an additional two and one-half

[1] ® Advanced Sterilization Products, a Johnson & Johnson company, Division of Ethicon, Inc., Irvine, CA.

minutes at which time it is compared to a color standard. If the color of the entire pad is equal to or darker than the color standard, the concentration of *ortho*-phthalaldehyde (OPA) in CIDEX® OPA Solution is above the minimum effective concentration (MEC). If any part of the pad is lighter than the color standard, the CIDEX® OPA Solution should not be used.

INTENDED USE

CIDEX® OPA Solution Test Strips are semi-quantitative chemical indicators used to determine whether the concentration of OPA in CIDEX® OPA Solution is above or below the MEC. CIDEX® OPA Solution Test Strips cannot be used to validate the disinfection process.

TECHNOLOGICAL COMPARISON TO THE PREDICATE DEVICE

CIDEX® OPA Solution Test Strips are used for determining OPA in CIDEX® OPA Solution whereas the CIDEX® Solution Test Strips are used for determining glutaraldehyde levels in CIDEX® Activated Dialdehyde Solution. Both tests have dry, reagent-containing paper indicator pads attached to plastic handles. Both pads contain an inhibitor that prevents reaction with an indicator at ineffective active ingredient concentrations.

The reaction pad of the CIDEX® OPA Solution Test Strips is observed three minutes after the strip is immersed in the solution while that of CIDEX® Solution Test Strips is read between five and eight minutes after immersion. For interpretation of the result, the indicator pad of the CIDEX® OPA Solution Test Strip is compared with a standard color block. The CIDEX® Solution Test Strips use a visual standard for interpretation of the result.

STATEMENT OF SUBSTANTIAL EQUIVALENCE

Eight individuals used CIDEX® OPA Solution Test Strips from three trial production lots in blind studies to test CIDEX® OPA Solution standards. Three of the readers were inexperienced in laboratory techniques. A total of 324 results were obtained with each standard.

At the MEC (0.30% OPA), 324 results were FAIL giving a specificity (lack of false PASS results) of 1.00. At 0.40% and 0.45% OPA, 322 and 324 results, respectively, were PASS. These results show that the CIDEX® OPA Solution Test Strips effectively indicate when the OPA concentration in CIDEX® OPA Solution is at the MEC of 0.3%.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. James E. Christner
Vice President, Research & Development
Serim Research Corporation
P.O. Box 4002
23565 Reedy Drive
Elkhart, Indiana 46514

Re: K992341
Trade Name: CIDEX® OPA Solution Test Strips
Regulatory Class: II
Product Code: JOJ
Dated: October 22, 1999
Received: October 26, 1999

Dear Mr. Christner:

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 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): K992341

Device Name: CIDEX* OPA Solution Test Strips

Indications For Use:

CIDEX* OPA Solution Test Strips are semi-quantitative chemical indicators used to determine whether the concentration of active ingredient in CIDEX* OPA Solution is above or below the minimum effective concentration of 0.3% OPA. CIDEX* OPA Solution Test Strips cannot be used to validate the sterilization or disinfection process.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ OR Over-The-Counter Use✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992341