K081370

510 (K) SUMMARY

JUL 11 2008

Prepared:	May 9, 2008
Submitter:	Serim Research Corporation
Address	P.O. Box 4002 Elkhart IN 46514
Phone: **Fax:**	574-264-3440 574-266-6222
Contact:	Patricia A. Rupchock Director of Regulatory Affairs
Device Trade Name:	Serim® DISINTEK™ OPA Test Strips
Common or Usual Name:	Indicator for ortho-phthalaldehyde (OPA) high level disinfectant
Device Classification Name:	Chemical Indicators for Liquid Chemical Germicide. (b) Class II (Physical/Chemical Sterilization Process Indicator).
Product Code:	JOJ
Class:	II
Regulation Number:	21CFR 880.2800
Substantial Equivalence:	The Serim DISINTEK OPA Test Strip is substantially equivalent to Cidex® OPA Solution Test Strip; K991709.
Device Description:	The device is a qualitative, single use, reagent test strip made up of a 0.40 inch square test pad that has been chemically treated to detect OPA in Cidex OPA Solution. The pad is affixed to one end of a 3.25 inch by 0.40 inch white opaque polystyrene strip.
Intended Use:	The Serim® DISINTEK™ OPA Test Strip is a chemical indicator for use in determining whether the concentration of *ortho-phthalaldehyde*, the active ingredient in Cidex® OPA Solution, is above or below the minimum effective concentration (MEC) established for Cidex OPA Solution.

Technological Characteristics: The Serim DISINTEK OPA Test Strips contains two reacting chemicals, a stabilizer, and other non-reacting ingredients. The reaction process involved with the test strip is based on a two step reaction. The first step involves a reaction in which a chemical at a concentration equivalent to 0.3% OPA (MEC) reacts with the OPA to form a colorless product. A second reaction then occurs in which OPA at levels above 0.3% reacts with a second chemical to form a colored compound, resulting in green color. The test pad size of 0.4" x 0.4" allows for easy interpretation of the change in color. The device will reliably indicate if the OPA concentration is above or below the MEC level of 0.3% OPA.

Performance: The performance of the Serim DISINTEK OPA Test Strips was evaluated in split samples blind studies and compared to test results obtained with Cidex OPA Solution Test Strips. The performance of the Serim DISINTEK OPA Test Strips is substantially equivalent to the predicate device, Cidex OPA Solution Test Strips.

Conclusion: The Serim DISINTEK OPA Test Strips have the same intended use as the predicate device. Both test strips measure the potency of OPA in Cidex OPA Solution, above or below the Minimum Effective Concentration of 0.3%. The Serim DISINTEK OPA Test Strips do not raise any new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2008

Ms. Patricia Rupchock
Director of Regulatory Affairs
Serim Research Corporation
3506 Reedy Street
Elkhart, Indiana 46561

Re: K081370
Trade/Device Name: Serim® DISINTEK™ OPA Test Strips
Regulation Number: 21 CFR 880.2800
Regulation Name: Indicator, Physical/Chemical Sterilization Process
Regulatory Class: Class II
Product Code: JOJ
Dated: May 9, 2008
Received: May 15, 2008

Dear Ms. Rupchock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-***[See Below For Phone Numbers]***. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K 081320

Device Name: Serim® DISINTEK™ OPA Test Strips

Indications For Use: The Serim® DISINTEK™ OPA Test Strip is a chemical indicator for use in determining whether the concentration of *ortho-phthalaldehyde*, the active ingredient in Cidex® OPA Solution, is above or below the minimum effective concentration (MEC) established for Cidex OPA Solution.

Prescription Use (Part 21 CFR 801 Subpart D)		AND / OR	Over-The-Counter Use (21 CFR 801 Subpart C)	√

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K 081320