K120652

510(K) SUMMARY

OCT 12 2012

Prepared: February 27, 2012

Submitter: Serim Research Corporation

Address P.O. Box 4002
Elkhart IN 46514

Phone: 574-264-3440
Fax: 574-266-6222

Contact: Patricia A. Rupchock
Director of Regulatory Affairs

Device Trade Name: RAPICIDE OPA-28 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 RAPICIDE OPA-28 Test Strip is substantially equivalent to Serim® DISINTEK™ OPA Test Strips, Serim Research Corporation, P/N 5121; K081370.

Device Description: The device is a qualitative, single use, reagent test strip made up of a 0.40 inch square indicator pad that has been chemically treated to detect OPA. The pad is affixed to one end of a 3.25 inch by 0.40 inch white opaque polystyrene strip.

Intended Use: The RAPICIDE OPA-28 Test Strip is a chemical indicator for use in determining whether the concentration of *ortho-phthalaldehyde,* the active ingredient in RAPICIDE OPA-28 Solution, is above or below the established Minimum Recommended Concentration (MRC) of 0.35%.

Technological Characteristics: The RAPICIDE OPA-28 Test Strip 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 reacts with the OPA to form a colorless product. A second reaction then occurs in which OPA in excess 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 MRC of 0.35% OPA.

Performance: The performance of the RAPICIDE OPA-28 Test Strips was evaluated in OPA solutions of Rapicide OPA-28 at the MRC and above in blind studies and compared to test results obtained with Serim® DISINTEK™ OPA Test Strips evaluated in Cidex OPA solutions at the MEC and above as well. The performance of the RAPICIDE OPA-28 Test Strips is substantially equivalent to the predicate device, Serim® DISINTEK™ OPA Test Strips.

Summary of Non-clinical Testing The following table summarizes the non-clinical testing performed to demonstrate that the Rapicide OPA-28 Test strip is safe and effective in monitoring the OPA concentration in Rapicide OPA-28 Disinfectant Solution.

Study	Result
Shelf Life	Passed
Open Bottle Stability	Passed
Effect of Contaminants	Passed
Effect of Temperature Deviation	Passed
Effect of pH Deviation	Passed
Analytical Specificity	Passed

Conclusion: The RAPICIDE OPA-28 Test Strips have the same intended use as the predicate device. Both test strips measure the potency of ortho-phthalaldehyde (OPA) in disinfectant solution, to determine whether it is above or below the Minimum Recommended or Effective Concentration. The difference between the proposed OPA indicator and the predicate device is its use with a different OPA based disinfectant. We are adding a new indication for use to the predicate device, namely the use in the RAPICIDE OPA-28 solution. This difference does not raise any new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 12 2012

Serim Research Corporation
Ms. Patricia Rupchock
Director of Regulatory Affairs
3506 Reedy Drive
Elkhart, Indiana 46514

Re: K120652
Trade/Device Name: Rapicide OPA-28 Test Strips
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: October 2, 2012
Received: October 4, 2012

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K12 0652

CONFIDENTIAL

INDICATIONS FOR USE

510(k) Number (if known): K

Device Name: RAPICIDE OPA-28 Test Strips

Indications For Use: The RAPICIDE OPA-28 Test Strip is a chemical indicator for use in determining whether the concentration of *ortho-phthalaldehyde*, the active ingredient in RAPICIDE OPA-28 Solution, is above or below the established Minimum Recommended Concentration (MRC) of 0.35%.

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

Elizabeth F. Claverie Weld
(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K120652