## 510(k) SUMMARY

K070419

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| Prepared: | August 30, 2007 |
| Submitter: | Hach Company |
| Address: | 23575 County Road 106<br>Elkhart, IN 46514<br>U.S.A.<br>(219) 262-2060 |
| Contact: | David A. Morris, Ph.D.<br>Director of Research |
| Device Trade/ Proprietary Name: | Opaciden® OPA Solution Test Strips |
| Device Common Name: | High Level Disinfectant (Indicator) |
| Classification Name: | Chemical Indicator for Liquid Chemical Germicide. 21CFR 880.2800 (b) Class II (Physical/Chemical Sterilization Process Indicator). Product Code: JOJ. |
| Predicate Device: | Browne Cidex™ OPA Indicator |
| Device Description: | The Opaciden OPA Solution Test Strip is a white polystyrene strip, of dimension 3.25 by 0.2 inch, with a 0.2 by 0.2 inch square yellow indicator pad at one end. It is intended for use exclusively with Opaciden OPA Germicide solutions to determine the germicide concentrations. The reagent pad is immersed in the sample and removed after 2 seconds. Excess sample is shaken off the pad and the strip is kept horizontal for 60 seconds. The chemical reagents in the indicator pad causes the pad to change color from yellow to magenta in OPA solutions with an ortho-phthalaldehyde concentration greater than the MRC of 0.3% OPA. |
| Intended Use: | The Opaciden OPA Solution Test Strips are a concentration monitor dedicated for use with Opaciden OPA Solution with a minimum recommended concentration of 0.3%. |

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Technological Characteristics:

*ortho*-Phthalaldehyde (OPA) reacts with sodium sulfite contained in the indicator pad to form a sulfite addition product and an equivalent amount of base. The increase in pH due to the reaction with OPA causes a color change of the pH indicator present in the pad. When the concentration of *ortho*-phthalaldehyde is greater than the MRC of 0.3%, a color change from light yellow to magenta occurs in the indicator pad of the OPA Opaciden Solution Test Strip. The pad of the predicate contains a different pH indicator that undergoes a different color change due to pH. The pad of the predicate device changes from light blue to purple when the OPA concentration is greater than 0.3%.

Assessment of Performance:

The performance characteristics of the Opaciden OPA Solution Test Strips were established by testing indicators in germicide solutions containing 0.3% and 0.4% *ortho*-phthalaldehyde. No false negatives were observed in solutions containing 0.4% ortho-phthalaldehyde. No false positives were observed in solutions containing 0.3% *ortho*-phthalaldehyde. The results of the testing indicate that the Opaciden OPA Solution Test Strips are suitable for their intended use.

Conclusion:

The Opaciden OPA Solution Test Strips are intended for exclusive use with Opaciden OPA germicide solution whereas the predicate device is intended for use with Browne Cidex OPA solution. The devices have the same intended use as concentration monitors for *ortho*-phthalaldehyde germicide solutions with a minimum recommended concentration of 0.3%. Both systems effectively measure the concentration of OPA in the germicide solutions that they are intended to monitor. The Opaciden OPA Solution Test Strips have no technological characteristics that raise new types of safety or effectiveness questions.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Dr. David A. Morris, Ph.D.
Director, Research and Technology
HACH Company
23575 County Road 106
Elkhart, Illinois 46514

Re: K070419
Trade/Device Name: Opaciden OPA Solution Test Strips
Regulation Number: 21 CFR 880.2800 (b)
Regulation Name: Physical/Chemical Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: August 12, 2007
Received: August 16, 2007

Dear Dr. Morris:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 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): 510(k) Number: K070419

Device Name: Opaciden OPA Solution Test Strips

Indications for Use:
The Opaciden OPA Solution Test Strips are a concentration monitor dedicated for use in ortho-phthalaldehyde-containing germicide solutions with a minimum recommended concentration of 0.3%. The Opaciden OPA Solution Test Strips are dedicated for use with the Ciden Opaciden OPA Solution.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheila A Murphy 10

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

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