MAY 27 2003

510(k) Summary (revised 5/03)

K012889

Banicide® Advanced
For Sterilization and High Level Disinfection

Pascal Company, Inc.
P.O. Box 1748
Bellevue, Washington 98009

Date of Summary: May 1, 2003

Contact Person

Vincent M. Tentarelli
425-827-4694

Name of Medical Device

Proprietary Name	Banicide® Advanced
Common or Usual Name	Single container glutaraldehyde solution for sterilization and high level disinfection
Classification Name	Liquid Chemical Sterilant/Disinfectant (Class II)

Substantial Equivalence to Predicate Product

Banicide Advanced is substantially equivalent to Wavicide 01, Cidex Plus 28-day Solution, and MetriCide 28 day Long-Life Activated Dialdehyde Solution. Substantial equivalence is based on the fact that Banicide Advanced has the same intended use (to sterilize and disinfect medical instruments) as the predicate products and relies on the same active ingredient (glutaraldehyde) to achieve the germicidal effect and has the same demonstrated efficacy. Banicide Advanced has a glutaraldehyde concentration and pH range comparable to that of Wavicide 01, Cidex Plus, and MetriCide. These products have comparable concentrations of glutaraldehyde (3.5% for Banicide Advanced, 2.65% for Wavicide 01, 3.4% for Cidex Plus, and 2.8% for MetriCide), and overlapping pH ranges. Banicide Advanced has demonstrated comparable sterilizing and disinfecting capabilities to the predicates. All three products are labeled with a 30-day or 28-day reuse period and require a chemical test strip to verify that the active ingredient remains at an effective concentration throughout the reuse period.

Indications for Use: Banicide Advanced is intended for use as a liquid chemical sterilant and/or a high level disinfectant to sterilize and disinfect medical devices and instruments in healthcare facilities when used according to the directions for use in the package insert.

Sterilant: Banicide Advanced is a sterilant when used in accordance with its directions for use for a maximum of 30 days at 25°C with an immersion time of at least 10 hours at its minimum effective concentration (MEC) of 1.8% glutaraldehyde.

High Level Disinfectant: Banicide Advanced is a high level disinfectant when used according to its directions for use for a maximum of 30 days at 25°C with an immersion time of at least 45 minutes at its minimum effective concentration (MEC) of 1.8% glutaraldehyde.

Reuse: Banicide Advanced can be reused for a period not to exceed 30 days provided the required conditions of glutaraldehyde concentration and temperature exist. The number of days in use should not be solely relied upon for assuring efficacy during its reuse period. A chemical indicator test strip is available for assuring that the glutaraldehyde concentration is at or above the MEC, 1.8%.

Material Compatibility: Glutaraldehyde solutions have a long history of compatible use with medical instruments made from a variety of materials without corrosive or other apparent damaging effects. The 510(k) includes documentation of this. A supplemental study was conducted and submitted showing that Banicide® Advanced is compatible with endoscopes under actual conditions of use.

Performance Testing: Banicide Advanced was evaluated in several efficacy tests after 30 days of manual stressing to simulate worst-case conditions encountered during its reuse. Banicide Advanced was tested for sporicidal, bactericidal, fungicidal, tuberculocidal, and virucidal activity, and the results are summarized below.

a. Sporicidal Tests

Banicide Advanced passed the AOAC Sporicidal Test against *B. subtillis* spores and *C. sporogenes* spores carried on silk suture loops and porcelain penicylinders in 10 hours at 22°C.

In a sporicidal test involving an end-point analysis of porcelain penicylinder carriers inoculated with *C. sporogenes*, Banicide Advanced was found to be sporicidal at 22°C and exposure times ranging from 8 hours to 11 hours.

In a spore rate-of-kill (D-value) test, Banicide Advanced was found to have a D-value of approximately one hour for *B. subtillis*.

Banicide Advanced will be re-tested prior to marketing to confirm that it passes a full-scale AOAC sporicidal test at 25°C and a glutaraldehyde concentration at or below the 1.8% MEC.

b. AOAC Use Dilution Test

S. aureus, P. aeruginosa, and *S. cholerasuis* dried onto steel penicylinder carriers were exposed to 30-day stressed Banicide Advanced in test tubes for 45 minutes at 22°C. No growth was observed on the carriers following exposure to Banicide Advanced.

c. AOAC Tuberculocidal Test

When tested under the quantitative tuberculocidal test protocol, stressed Banicide Advanced was found to achieve a six log reduction in *Mycobacterium bovis* in 45 minutes at 25°C.

d. AOAC Fungicidal Test

When tested under the AOAC Fungicidal test protocol, stressed Banicide Advanced was found to kill *Trichophyton mentagrophytes* within 45 minutes at 22°C.

e. Simulated In-Use Test

In a test designed to simulate the actual use of stressed Banicide Advanced on medical devices, Banicide Advanced effectively disinfected flexible fiber optic endoscopes with no microorganisms recovered from the instruments after 45 minutes of exposure at 22°C.

f. Virucidal Efficacy Tests

Stressed Banicide Advanced was shown to be effective against the following viruses: Cytomegalovirus, Coxsackievirus B-6, Hepatitis A, Influenza A2, Poliovirus Type II, Rhinovirus Type 14, Rotavirus Type WA, Respiratory Syncytial Virus, Herpes Simplex Types I and II, Duck Hepatitis B, Human Immunodeficiency Virus (HIV), and Adenovirus Type 5 in 45 minutes at 25°C.

g. In-Use Test

Banicide Advanced was shown to be an effective high level disinfectant when tested on a variety of endoscopes taken from an actual clinical setting.

Safety

Studies conducted by Union Carbide on the safety of glutaraldehyde are summarized and cited. It is demonstrated through exhaustive extraction testing that residues of glutaraldehyde on treated instruments will not present a safety risk to patients or health care workers who come into contact with the instruments.

Exposure to glutaraldehyde may produce toxic, irritant, inflammatory and allergic responses. Warnings and precautions in labeling can adequately inform users of these hazards. The personnel handling Banicide Advanced will be medical professionals, or healthcare personnel trained to handle glutaraldehyde products. Although the concentrations being handled are not highly toxic, they may be irritating. Warning and precaution statements must be read and followed. In sum, Banicide Advanced is a safe and highly effective product when used in accordance with its labeled directions for use and precautionary information.

Testing of the Indicator Strip

Pascal has confirmed through testing that the 3M Cold Sterilog™ 2.1% test strip is compatible with Banicide Advanced. A sample of Banicide Advanced solution was stressed by the addition of fetal bovine serum and diluted with hard water. Sets of 60 test strips were tested at each of 6 different concentrations, 2.4%, 2.3%, 2.2%, 2.0%, 1.8%, and 1.7% glutaraldehyde. Test strip readings were taken at 4, 5, 8, and 9 minutes. No positive readings were obtained at the MEC of 1.8% or at 1.7% glutaraldehyde. Further analysis of the results was provided to FDA.

Product Comparison

A comparison of key features of Banicide Advanced with the predicates, Wavicide, Cidex Plus, and MetriCide is presented in the table below. The information regarding Wavicide, MetriCide, and Cidex Plus is taken from publicly available 510(k) summaries and labeling.

Features	Banicide Adv.	Wavicide 01	MetriCide	Cidex Plus
target glutaraldehyde concentration of use dilution	3.5%	2.65%	2.5%	3.4%
claimed minimum effective concentration	1.8%	1.7%	1.8%	2.1%
reuse period	30 days	30 days	28 days	28 days
exposure conditions for sterilization	10 hours 25°C	10 hours 22°C	10 hours 25°C	10 hours 20-25°C
exposure conditions for high level disinfection	45 minutes at 25°C	45 minutes at 22°C	90 minutes 25°C	20 minutes 25°C
dilution required	no	no	no	no
activation required	no	no	yes	yes
test strip available	yes	yes	yes	yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2003

Pascal Company, Incorporated
C/O Mr. David Joy
Keller and Heckman LLP
1001 G Street, N.W., Suite 500 West
Washington, DC 20001

Re: K012889
Trade/Device Name: Banicide® Advanced
Regulation Number: 880.6885
Regulation Name: Liquid Chemical Sterilants/High Level Disinfectants
Regulatory Class: II
Product Code: MEB
Dated: February 27, 2003
Received: February 27, 2003

Dear Mr. Joy:

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 (301) 594-4618. 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/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012889

Device Name: Banicide® Advanced

Indications For Use:

Banicide® Advanced is a reusable liquid chemical sterilant/high level disinfectant intended to (1) sterilize medical instruments at an exposure time of 10 hours and an exposure temperature of 25°C and a minimum effective concentration of 1.8% glutaraldehyde; and (2) provide high level disinfection at an exposure time of 45 minutes and an exposure temperature of 25°C and a minimum effective concentration of 1.8% glutaraldehyde. It may be re-used for a period of 30 days provided the solution remains above the MEC as confirmed by a chemical indicator test strip.

(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 Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K012889