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510(k) SUMMARY - Revised

FEB - 4 2009

Owner's Information:	IRRIMAX Corporation 1792 Bell Tower Lane Weston, FL 33326 Tel: (404) 317-9335 Fax: (678) 225-5877
Contact Person:	Julie Stephens, President/Consultant Regulatory Resources Group, Inc.
510(k) Number:	K080779
Date Prepared:	August 2008
Trade/Proprietary Name:	IRRISEPT™ Wound Debridement and Cleansing System
Common Name:	Wound Cleanser
Classification Name:	Jet Lavage, Class II, 21 CFR 880.5475
Product Code:	FQH
Legally Marketed Predicate Devices:	MicroKlenz™ Antimicrobial, Deodorizing Wound Cleanser, 510(k) #: K022670; DermaGran® Wound Cleanser, 510(k) #s: K970660, K954743, K945802; BioPatch® CHG Dressing, 510(k) #: K003229

Device Description:

IRRISEPT™ Wound Debridement and Cleansing System is a manual, self-contained irrigation device with 0.05% Chlorhexidine Gluconate (CHG) solution. The mechanical action effectively loosens and removes wound debris. The CHG acts as a preservative to help inhibit microbial growth in the solution.

The IRRISEPT™ Wound Debridement and Cleansing System is straightforward and uncomplicated to use. The User opens a prepackaged box, which contains one bottle and one splashguard. The bottle is opened by twisting off its "T" cap seal. The splashguard is then removed from its pouch and screwed directly onto the bottle. The IRRISEPT™ Wound Debridement and Cleansing System is now ready for use. The IRRISEPT™ Wound Debridement and Cleansing System can produce 7-8 psi of pressure as recommended by American College of Emergency Physician's (A.C.E.P) for effective wound cleansing/irrigation. This pressure is sufficient to agitate, loosen and remove debris from wounds.

The ingredients of the solution are 0.05% Chlorhexidine Gluconate (CHG) in Sterile Water for Irrigation, USP (99.95%).

Intended Use:

The IRRISEPT™ Wound Debridement and Cleansing System is a wound cleansing delivery system. The mechanical action effectively loosens and removes wound debris.

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Similarities and Differences of the Proposed Devices to the Predicate Devices:

Similarities
The IRRISEPT™ Wound Debridement and Cleansing System is substantially equivalent in intended use and method of use to the predicate devices. The preservative present in the IRRISEPT™ solution, Chlorhexidine Gluconate (CHG), is equivalent to Johnson & Johnson's predicate device, BioPatch® CHG Dressing, and has been utilized extensively in the marketplace.

Differences
The IRRISEPT™ Wound Debridement and Cleansing System differs in its mechanical action because it utilizes a patented multi-port splashguard that screws onto the bottle to irrigate the wound while the predicate devices use either a pump-spray bottle or they directly pour the fluid onto the wound site.

Conclusion:

The IRRISEPT™ Wound Debridement and Cleansing System has the same intended use, principles of operation, and technological characteristics as the predicate devices. The IRRISEPT™ Wound Debridement and Cleansing System was developed with Chlorhexidine Gluconate, a proven effective preservative, already premixed and packaged for ease of use on wounds.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 4 2009

IRRIMAX Corporation
% Regulatory Resource Group, Inc.
Ms. Julie Stephens
111 Laurel Ridge Drive
Alpharetta, Georgia 3004

Re: K080779
Trade/Device Name: IRRISEPT™ Wound Debridement and Cleansing System
Regulation Number: 21 CFR 880.5475
Regulation Name: Jet lavage
Regulatory Class: II
Product Code: FQH
Dated: January 12, 2009
Received: January 13, 2009

Dear Ms. Stephens:

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) 276-0115. 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,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use - Revised

510(k) Number (if known): K080779

Device Name: IRRISEPT™ Wound Debridement and Cleansing System
IRRIMAX Corporation

Indications For Use:

The IRRISEPT™ Wound Debridement and Cleansing System is a wound cleansing delivery system. The mechanical action effectively loosens and removes wound debris.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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 General, Restorative, and Neurological Devices

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