

MAY 28 1999

1K9908441

510(k) SUMMARY

***StarDental*[®] Air Controlled Sterile Irrigation System**

Company:

***StarDental*[®], Division of DentalEZ[®]
Owner/operator number 2520265**

Contact Person:

Frank Oellig
Product Development Engineer
StarDental[®], Division of DentalEZ[®]
1816 Colonial Village Lane
Lancaster, PA 17601
Phone: (717)-291-1161
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CONFIDENTIAL

Device Trade Name:

***StarDental*[®] aXcs Sterile Water System**

Common or Usual Name:

Dental Accessories

Predicate Devices:

SteriWater System, Lares, NSK, Satelec and other manufacturers of water delivery systems.

Description/Intended Use:

The *StarDental*[®] **Air Controlled Sterile Irrigation System** is used intra-orally by trained dental professionals for delivery of sterile water for oral surgical procedures as a replacement irrigating solution to the dental operative unit's water supply, specifically for cooling a dental rotary instrument.

Substantial Equivalence:

The **Air Controlled Sterile Irrigation System** as submitted is substantially equivalent to SteriWater, AquaSept and Surgic II currently being marketed by Waggoner Dental Manufacturing, Lares and NSK and additionally substantially equivalent to Suprasson P Max and Suni currently being marketed by Satelec and other water delivery systems currently being marketed by Baxter and Abbott Labs. Materials used to manufacture the components are similar. Means of operation are similar, compressed air controls the pinch valve while electrical signal controls the solenoid valves. The main difference in design is that the **Air Controlled Sterile Irrigation System** consists of a connector assembly and pinch valve assembly which can be autoclaved as compared to a SteriWater which must be disassembled and autoclaved and also infusion pumps that utilize disposable components.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 28 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Frank Oellig
Product Development Engineer
StarDental®, Division of DentalEZ®
1816 Colonial Village Lane
Lancaster, Pennsylvania 17601

Re: K990844
Trade Name: StarDental®, aXcs Sterile Water System
Regulatory Class: I
Product Code: EIA
Dated: March 12, 1999
Received: March 15, 1999

Dear Mr. Frank Oellig:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Intended Use

The **Air Controlled Sterile Irrigation System** is used by dental professionals for delivery of sterile water for oral surgical procedures, specifically for cooling a dental rotary instrument.

CONFIDENTIAL

Prescription Use _____
(Per 21 CFR 801.109)

Prescription Use _____
(Per 21 CFR 801.109)

Susan Purvis

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number 12990844