K021378

JUN 7 2002

Star Dental Products
1816 Colonial Village Lane
Lancaster, PA 17601-5864
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510(k) SUMMARY

Portable HDX Intraoral X-ray
April 29, 2002

1. **Company:**
   ***StarDental*®, Division of DentalEZ®**
   Owner/operator number 2520265

   Contact Person:
   Deon Beck
   Manufacturing Engineer
   StarDental®, Division of DentalEZ®
   1816 Colonial Village Lane
   Lancaster, PA 17601
   Telephone: 717-291-1161
   Facsimile: 717-391-2757

2. **Proprietary-Trade Name:** Portable HDX Intraoral X-ray
   Classification Name: Extraoral source x-ray system (per 21 CFR section 872.1800)
   Common/Usual Name: Portable Dental X-ray

3. **Predicate Devices:**

   MinXray HF70D (K000061)
   Literature is included at Tab 4.

4. **Description:**

   Portable HDX Intraoral X-ray is a portable dental x-ray system that operates on 120 VAC (+/-10%), 60 Hz, and 240 VAC (+/-10%), 50 Hz line AC power. The system uses Constant Emission Power (CEP) which allows for minimum exposure time and can be either mounted to a tripod or can be hand held.

5. Intended Use:

Portable HDX Intraoral X-ray is to be used only by a qualified/trained dentist or dental technician on both adult and pediatric subjects for taking diagnostic extraoral dental x-rays using intraoral image receptors. The usual safety precautions regarding the use of x-rays must be observed by the operator.

6. Safety and Effectiveness, comparison to predicate device:

The result of bench and user testing per Performance Standards 21 CFR § 1020.30 and United States Government Specifications SP0200-96-R-8076 (NSN 6525-01-425-5216) indicates that the new system is as safe and effective as the predicate devices.

7. Substantial Equivalence Chart:

Feature	Portable HDX Intraoral X-ray	MinXray HF70D
Intended Use:	Extraoral dental x-ray w/intraoral receptors	SAME
Energy Source:	120V 50 Hz or 240V Hz AC	120V 50-60 Hz AC
Size:	Body: 5.5" H x 8.25 W x 8" D Cone: 2.75" Dia. x 5.75" L	Body: 5.8" H x 4.8" W x 7.9" D Cone: 2" Dia. x 6" L
Weight:	11.7 lbs.	10.4 lbs.
User Interface:	Up-down buttons for exposure time selections with display.	Up-Down pushbuttons for three kVp selections and exposure time selection with indicators.
Exposure Times:	0.01 – 2.00 seconds in 0.01 increments	0.02 – 1.98 seconds in 99 steps
mA:	7 mA	10 mA
kVp:	65 kVp	60, 65, 70 kVp
Performance Standard:	21 CFR 1020.30, United States Government Specifications SP0200-96-R-8076 (NSN 6525-01-425-5216)	21 CFR 1020.30
Electrical Safety:	UL 2601, CSA 601-M90, EN 6061-1:1990+A1+A2	UL 2601, IEC 6061-1

8. Conclusion:

After analyzing all testing data and meeting performance standards and specifications it is the conclusion of DentalEZ that the "Portable HDX Intraoral X-ray" is as safe and effective as the predicate device. The system has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 7 2002

Mr. Deon Beck
Manufacturing Engineer
Dental EZ Group
Star Dental Products
1816 Colonial Village Lane
LANCASTER PA 17601-5864

Re: K021378
Trade/Device Name: Portable HDX Intraoral X-ray system
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: 76 EHD
Dated: April 29, 2002
Received: May 1, 2002

Dear Mr. Beck:

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 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 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 one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K021378

Statement of Intended Use:

The Portable HDX Intraoral X-ray unit is intended for use only by a qualified/trained dentist or dental technician on both adult and pediatric subjects for taking diagnostic extraoral dental x-rays using intraoral image receptors.

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021378