JAN - 6 2005

Dec 17, 2004

510(k) k043136 Summary

Applicant:

Dental X-Ray E.U.
Calle 49 Sur N° 43A 26-Local 301
Envigado Antioquia, Colombia
Tel. 4-302-3535 – Fax. 4-302-4353
Owner/Operator Number: 9063785

Preparer:

Dental Products of USA, Inc.
1460 NW 107 Ave Suite G
Miami, Florida 33172
Tel: 305-640-9894 Fax: 305-477-3206
Contact Person: George Echeverri
Owner/Operator Number: 9034594

Summary Prepared Date:

Dec 17, 2004

Device Name:

I. *Proprietary Name:* *Elity 70 X-Ray*
II. *Common/Usual Name:* *Unit, X-Ray, Extraoral with Timer*
III. *Classification Name:* *Unit, X-Ray, Extraoral with Timer*

Predicate Devices:

I. *Corix 70 Plus-USV K031802*
II. *A/T X-Ray 70 K024285*
III. *Image X-70 Plus K000551*

K043136

Intended Use:

The Elity 70 X-Ray is an extra oral source X-Ray system for dental radiographic examination and diagnosis of diseases of the teeth. The unit is intended for use in the dental clinic environment and used by trained dentists and/or assistants.

Device Description:

The Elity 70 X-ray Unit is a traditional extra oral radiographic system, designed to face the most demanding needs of the dental profession both when using traditional films and digital imaging receptor. The system voltage potential of 70kVp and the anodic current of 10 mA, the small focal spot, the beam limiting device with effective near focus collimation, and the penetration power of a 70 kVp radiation beam make the best combination of which grant sharp images. The Elity 70 X-Ray wall mounted system feature short, medium, and long extension arms giving a useful reach up to 185 cm when combined with the folding arm. The system comes with an Auto Set timer thus offering the best flexibility of use. Common functionality include a green light for "system ready", a yellow light and a buzzer for "radiation emission, and a red light for "faulty condition"; each timer and each hand switch can be remotely mounted. The high voltage generator is enclosed in a cover. A circular cone with a maximum diameter of 60 mm forms the beam-limiting device. The weight of the tubehead is 7.5 kg. The certified components may be assembled in different configurations in terms of arms and mounting.

Auto Set electronic timer microprocessor controlled, with flat keyboard; automatic setting of exposure time from 0.1 ms to 3.0 through object-programmed selection according to tooth type and patient size. Elity 70 extra-oral X-ray equipment is composed of the following parts:

I. *Fixed and Scissor Arms.*

II. *Tubehead with Beam Limiting Device.*

III. *Control Panel (Timer)*

IV. *Wall Mount Kit- Single post 16" Center Wall Plate.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 6 2005

Dental X-Ray E.U.
% Mr. George Echeverri
Director
Dental Products of USA, Inc.
1460 NW 107 Ave, Suite G
MIAMI FL 33172

Re: K043136
Trade/Device Name: Elity 70 X-Ray Unit
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: 90 EHD
Dated: December 17, 2004
Received: December 20, 2004

Dear Mr. Echeverri:

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 (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 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.

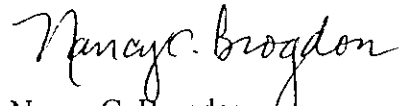
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,



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

Enclosure

Indications for Use

510(k) Number (If know): K043136

Device Name: Elity 70 X-Ray

Statement of Indications for Use:

Intended Use for the Elity 70 X-Ray Unit:

The Elity 70 is an extraoral device designed to expose intraoral X-ray recording media (Film, plates, sensors) for the purpose of radiographic examination and diagnosis of the teeth.

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)

David R. Hyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043136