DEC 1 3 2004

510(k) Summary K043092

as required by CFR section 807.92(c)

I. General Information

Date: November 6, 2004

Applicant: Progeny, Inc.
1807 Barclay Blvd.
Buffalo Grove, Ill.
60089

Contact Person: Alan Krema

Telephone: 847-850-3800 x785

Fax: 847-850-3800

II. Names

Device Name:

Trade Name: PREVA
Common Name: Intra Oral X-Ray System
Classification Name: 76 EHD – Unit, X-Ray, Extra oral with Timer

III. Predicate Devices

Gendex Gx-770
Gendex 765DC

IV. Product Description

The Progeny, Inc. PREVA Intraoral Dental X-Ray System is an extraoral source of x-rays for intraoral radiographs in dental diagnostic radiography.

The Progeny, Inc. PREVA Intraoral Dental X-Ray System consists of the following main components:

K043092

X-ray tubehead
Rotating yoke for tubehead mounting
Articulation arm
Horizontal extension arm
Electronic control unit
Wall mount
8 inch cone

Optional Components:

12 inch cone
8 ft. coil cord with exposure switch

The Power supply is regulated to provide a selectable 60, 65, or 70 kVp at a selectable tube current of 4, 6,or 8 mA. Predefined exposure times may be selected via the operator control panel. The range of exposure times is 0.01 to 2.00 seconds.

V. Indications for Use / Rationale for Substantial Equivalence

The PREVA Intraoral Dental X-Ray System is to be used as an extraoral source of x-rays in Dental radiography.

The PREVA shares the same indications for use, materials, design, operational and functional features and is therefore substantially equivalent to the predicate devices listed in section III of this summary.

There are several major independent manufacturers of Intra Oral diagnostic Radiographic Systems on the U.S. market. One is the Dentsply Gx770. The 510(k) number is K935046 . The classification of the Dentsply device is listed as product code 76EHD.

The other currently marketed device is the Gendex 765, manufactured by Dentsply, Inc. the 510(k) number is K992610. The classification of the Gendex 765 is listed as product code 76EHD .

Labeling for the currently marketed devices is included as Appendix B.

Comparison Table: K043092

Characteristic	Gx 770	Gendex 765	Progeny PREVA
Kv	70 kVp fixed	65 kVp fixed	60, 65, 70 kVp, selected
mA	7.0 mA	7.5 mA	4, 6, 8mA, selected
Operator Technique Selection	Exposure Duration Only	Exposure Duration Only	kV, mA, Exposure Duration
Suspension	Articulated Arm	Articulated Arm	Articulated Arm
X-Ray Field Size	6.5 cm diameter	6.0 cm diameter	6.5 cm diameter
Focal Distance	8 in. cone 12 in. cone	8 in. cone	8 in. cone 12 in. cone
Operator Exposure Control	Deadman Switch	Deadman Switch	Deadman Switch

VI. Safety and Effectiveness Information

Safety and effectiveness is demonstrated by:

Performance testing and verification to meet product specifications.
Software testing to validate software design and performance.
Hazard analysis and risk level assessment.
Same indications for use as predicate devices.

All of the above steps and evaluations combine to demonstrate that the PREVA Intraoral Dental X-Ray System is safe and effective when the device is used as labelled.

K043072

VII. Conclusion

The Progeny, Inc. PREVA Intraoral Dental X-Ray System is determined to be substantially equivalent to the predicate devices, the Gendex Gx-770, and the Gendex 765DC. The PREVA shares the same indications for use, materials, design, operational and functional features to the currently marketed predicate devices listed in section III of this summary. The PREVA Intraoral Dental X-Ray System is safe and effective when the device is used as labelled.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2004

Mr. Alan Krema
Director of Product Development
Progeny, Inc.
1407 Barclay Blvd.
BUFFALO GROVE IL 60089

Re: K043092
Trade/Device Name: PREVA Extraoral X-Ray System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: 90 EHD
Dated: November 3, 2004
Received: November 15, 2004

Dear Mr. Krema:

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

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 known): K043092

Device Name: PREVA

Indications For Use:

The intended use of the Progeny PREVA Extra-Oral X-Ray system is to act as a diagnostic source for radiographic dental imaging.:

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K043092