AUG - 9 2004

510 (k) Summary

As required by CFR section 807.92(c)

I. General Information

Date: July 2, 2004

Applicant: Progeny Inc.
1407 Barclay Blvd.
Buffalo Grove, IL 60089

Contact Person: E. M. Dolan

Telephone: 847.850.3800, ext. 240

Fax: 847.459.5175

II. Names:

Device Name:

Trade Name:	MPSe
Common Name:	Progeny MPSe
Classification Name:	Unit, X-ray Intraoral

III. Predicate Devices

Schick Technologies Inc. CDR
VisioDent RSV
Durr Dental Vista Ray
Trophy RVG

IV. Product Description

The X-ray MPS system is an intraoral receiver of the X-ray energy used by the dentist to image teeth and the oral cavity. The MPSe sensor consists of 3 pieces: an X-ray sensor (#1 or #2), an X-ray sensor driver and a power supply.

The Progeny MPSe Intraoral X-ray System consists of the following main components:

Sensor
X-Ray sensor driver
Power Supply

Accessories and Part Numbers

X-ray sensor: By the number of the pixel array the CCD X-ray sensors that can be used with the MPSe driver are two. Number 1 has a matrix of 912 x 1368 (1.25 million pixels) and number 2 has 1250 x 1640 (2.05 million pixels).

X-ray sensor driver: The driver module is a stand-alone or wall mounting microprocessor unit that receives the X-ray image from the sensor and is transferred to a network storage device or display at a local display if the option is available.

Power Supply: This is a medical certified unit that has 110-240V AC input and 12V output. Power Supplies that are also acceptable include medical certified power supply units with the output range of 6V to 26V.

Other Devices

The intraoral X-ray Sensor is intended for use in a Local Area Network in communication with storage devices such as Personal Computers or Laptops that are connected to the local network.

V. Indications for Use / Rationale for Substantial Equivalence

The MPSe System is to be used as an intraoral receiver of X-rays in Dental radiography.

The MPSe shares the same indication 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 Intraoral Diagnostic Radiographic Systems on the US market. One is the Trophy Radiologie RVG. The 510(k) number is K950533. The classification of the Trophy Radiologie device is listed as product code EAP.

The other currently marketed device is the Schick Technologies CDR. The 510(k) number is K933455. The classification of the Schick Technologies CDR is listed as product code EAP.

Labeling for the currently marketed devices is included in section 2 of this document.

There are several major independent manufacturers of Digital Intra Oral X-ray systems. In the comparison table below are listed the most popular products from Schick Technologies, VisioDent, Durr Dental and Trophy in comparison to the Progeny MPSe digital X-ray system.

Comparison Table:

Characteristic	Schick Technologies Inc.	VisioDent	Durr Dental	Trophy	Progeny Inc.
Product Name	CDR	RSV	Vista Ray	RVG	MPSe
Number sensors	3	2	2	2	2
Sensor size [mm]	31 x 22 37 x 24 43 x 30	- 39 x 25 42 x 32	- 25 x 36 32 x 42	- 41 x 25 45 x 32	- 35 x 26 41 x 31
Technology	CMOS	CCD	CCD	CCD	CCD
Interface to PC	USB	USB	EPP	USB	Ethernet, WLAN
Dynamic Range	4096:1	4096	4096:1	4096:1	65536:1
Distance between Device & PC	-	5	5 or 30	-	Unlimited*
Sensor Cable length [m]	2	2	2.5	2	2

* Regarding IEEE802.3 Standard

VI. Safety and Effectiveness Information

In these safety instructions the word "system" refers to the Progeny MPSe and its accessories.

1. **Read Instructions First:** Please read and follow the safety and operating instructions before operating the system.
2. **Retain Instructions:** Keep the safety and operating instructions in a safe place for future reference.
3. **Obey All Warnings:** Warnings and cautions on the system and in safety and operating instructions must be adhered to.

4. **Following Instructions:** If you have difficulty following or understanding the instructions in this booklet, call your dealer or supplier.
5. **Cleaning:** Unplug the system Power Cord from the wall outlet before cleaning. Do not spray any aerosol or non-aerosol sprays into the control unit or power supply. If necessary, wipe off the exterior with soap and water on a damp cloth. Sterilization or disinfecting should be done only as recommended in the Section "Cleaning and Sterilization."
6. **Moving:** Do not place on an unstable surface. A system and cart combination should be moved with care. Quick stops, excessive force, and uneven surfaces may cause the system and cart combination to overturn. Locate your system on a secure platform and avoid jarring the system while in operation.
7. **Power Sources:** The system is shipped with an external DC power supply, and a three-wire grounding type plug (a plug having a third pin for grounding). The 3-pronged plug must be operated only from standard 3-prong grounded wall outlets. If you are not sure of the type of power supply to your office, consult your local power company.
The Power Supply will accept AC inputs in the range of 100-240 Volts, 50 or 60 Hz. In order to connect to the electrical power in a specific area, a detachable cord set with its' power plug approved for the particular AC receptacle must be used. This must be a Class I, 3-Wire, grounded connection.
8. **Power Cord and Handpiece Cable Protection:** The power cord and handpiece cable should be routed so that they are not likely to be walked on, pinched or kinked by items placed upon or against them. This may damage the cords and prevent the system from working properly. Pay particular attention to plugs and the point from which the cords exit the system.
9. **Lightning:** For added protection of this system during a lightning storm or when it is left unattended and unused for long periods of time, disconnect it from the wall outlet. This will prevent damage to the system due to lightning and power line surges.
10. **Servicing:** Except for the replacement of light bulbs, do not attempt to service this system yourself. Opening or removing covers may expose you to dangerous voltage or other hazards and may damage the system and void the warranty.
11. **Ventilation:** Openings in the system cabinet are provided to ensure proper ventilation. These openings must remain unobstructed at all times. Use caution when stacking the system near other equipment to ensure the normal operating temperature is not exceeded. Do not install this product into a closed rack or cabinet. Never place objects in or near openings in the cabinet.

CAUTION:
Never place the system on a soft surface that might block the ventilation openings in the bottom of the control unit.

12. **Fluids:** Keep fluids away from the system to avoid damage resulting from inadvertent spills.
13. **Storage:** Store the unit in temperatures of 10-40° C (50-104° F), humidity 0-90%.

14. **Flammable Anesthetics:** This equipment is not suitable for use with flammable anesthetics.
15. **Mode of Operation:** The mode of operation is continuous intermittent.
16. **Degree of Protection:** The degree of protection is ordinary for this equipment.
17. **Auxiliary Equipment**: To insure continued protection from electric shock from leakage currents, it is important to connect only to medical grade auxiliary equipment. Any auxiliary equipment must have a statement: "Any TV, VCR, Printer, etc. must comply with the requirements on EN60601."
18. **Damage Requiring Service:** Disconnect the system from the wall outlet and refer servicing to Progeny Inc. under any of the following conditions:
(a) If the power cord or handpiece cable is damaged.
(b) If liquid has been spilled onto, or objects have fallen into the system.
(c) If the system does not operate normally even if you follow the operating instructions. Adjust only those controls that are covered by the operating instructions. Improper adjustment or operation may result in damage and may require extensive work to restore the system to its normal operation.
(d) If the product has been dropped or the cabinet has been damaged.
(e) If the system exhibits a distinct change in performance.

CAUTION:
Do not attempt to remove the covers or service this product yourself. Dangerous voltages and hazards exist inside. Only the internal battery can be serviced in the field. Refer to the Battery Replacement section for battery replacement. There are no other field serviceable parts inside your system. Refer all servicing to Progeny Inc.

VII. Conclusion

The Progeny MPSe System is determined to be substantially equivalent to the predicate devices, the Schick Technologies CDR, The VisioDent RSV, The Durr Dental Vista Ray, and the Trophy RVG. The MPSe System is safe and effective when the device is used as labeled.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 9 2004

Mr. E. M. Dolan
Director of Quality
Progeny, Inc.
1407 Barclay Blvd.
BUFFALO GROVE IL 60089

Re: K041831
Trade/Device Name: Progeny MPSe Intraoral Dental X-ray Sensor
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: 90 MUH
Dated: July 2, 2004
Received: July 19, 2004

Dear Mr. Dolan:

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 Office of Compliance at one of the following numbers, based on the regulation number at the top of the 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" (21CFR Part 807.97) you may obtain. 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

510(k) Number (if known): K041831

Device Name: Progeny MPSe Intra-oral Dental X-ray Sensor

Indications For Use:

Statement of Indication for Use:

Intended Use:

The Progeny MPSe system is intended to use for acquisition of digital images of intra-oral tissue including teeth on a CCD X-ray sensor, and transmit images to a computer for display by Ethernet.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041531