K092537

Section 5. 510(k) Summary

AUG 2 7 2009

I. General Information

Date: May 30,2008

Applicant: TOSHIBA AMERICA ELECTRONIC COMPONENTS,INC.
2150 EAST LAKE COOK RD.,SUITE 310 BUFFALO GROVE,IL 60089,UNITED STATES

Contact Person: JOHN-KURZYDLO
Telephone: 847-4847092
Fax: 847-5417287

II. Names:

Device Name:

Trade Name: Digital X-ray Sensor
Common Name: Intraoral X-ray Sensor
Classification Name: X-ray Image Sensor

III. Predicate Devices

Trophy Radiologie RVG
Schick Technologies Inc. CDR
Video Dental Concepts, Inc. Dentron Sensor

IV. Product Description

The Digital X-ray Sensor is an intraoral receiver of X-ray energy used by the dentist to obtain instant digital images of teeth and the oral cavity of patients. Images are transmitted to a computer for display.

The Digital X-ray Sensor is composed by following components:

1) Sensor head
2) Controller
3) USB cable
4) Driver software

Accessories and Part Numbers

	Part number	Description	Dimensions
Sensor head	E9539	Size 1, soft cover	See 11-3-1
	E9505	Size 1, hard cover	See 11-3-2
	E9502	Size 2, soft cover	See 11-3-3
	E9540	Size 2, hard cover	See 11-3-4
Controller	ECU-D001A	Sensor head control unit	See 11-3-5
USB cable	ECB-D002A	Cable between controller and PC	See 11-3-6
Driver software	-	Software to drive controller	-

V. Indications for Use / Rationale for Substantial Equivalence

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

The Digital X-ray Sensor 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 K0721349. The classification of the Schick Technologies CDR is listed as product code MQB.

And the other currently marketed device is the Video Dental Concepts, Inc. Dentron sensor The 510(k) number is K080738. The classification of the Video Dental Concepts, Inc. Dentron sensor is listed as product code MUH and MQB.

In the comparison table below are listed from Trophy Radiologie, Schick Technologies, Inc. and Video Dental Concepts, Inc. in comparison to the Digital X-ray Sensor system.

Comparison Table:

Characteristic	**Tropy Radiologie**	**Schick Technologies Inc.**	**Video Dental Concepts, Inc.**	**Toshiba**
Product Name	RVG	CDR	Dentron Sensor	Digital X-ray Sensor
Number sensors	2	3	2	4 two for size 1 and two for size 2
Sensor size [mm]	- 41 x 25 45 x 32	31 x 22 37 x 24 43 x 30	30 x 20 34 X 24	Size 1 40.1 x 25.1 Size 2 soft 44.4 x 32.6 Size 2 hard 43.7 X 31.9
Technology	CCD	CMOS	CCD	CMOS
Inerface to PC	USB	USB	USB	USB
Dynamic Range	4096:1	4096:1	4095 1	4096:1
Distance between Device & PC	-	-	-	Less than 7.5m
Sensor Cable length[m]	2	2	-	2.5

VI. Safety and Effectiveness Information

In these safety instructions the word "system" refers to the Digital X-ray Sensor **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 oniy 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 Digital X-ray Sensor System is determined to be substantially equivalent to the predicate devices, the Trophy Radiologie RVG, the Schick Technologies, Inc. CDR, and the Video Dental Concepts, Inc. Dentron sensor. Digital X-ray Sensor System is safe and effective when the device is used as labeled.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

AUG 2 7 2009

Toshiba America Electronic Components, Inc.
% Mark Job
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota, 55313

Re: K092537
Trade/Device Name: *Digital X-ray Sensor E9502, E9505, E9539, and E9540*
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: August 18, 2009
Received: August 19, 2009

Dear Mr. Job:

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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting 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): K092537

Device Name: Digital X-ray Sensor

Indications For Use:

Toshiba Digital X-ray Sensor is an intraoral receiver of X-ray energy by the dentist to obtain instant digital images of teeth and the oral cavity of patients. Images are transmitted to a computer for display.

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)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092537