K992896

SEP 3 1999

Section E – 510(k) Summary

Submitted by:	Jim Jacobson Dental X-ray Support Systems 2124 196th Street SW, Suite B Lynnwood, WA 98036 Phone: 888-230-9500 Fax: 425-640-2176
Date Submitted:	08/06/99
Trade Name:	*DXSS* Automatic X-ray Film Processor
Common Name:	Film Processor
Classification Name:	Dental Automatic Radiographic Film Processor (Per 21 CFR section 892.1900)
Substantial Equivalence:	Gendex Processor K945682 02/09/95
Description of Device:	Dental automatic radiographic film processor
Intended Use:	The *DXSS* Automatic X-ray Film Processor is an automatic radiographic film processor, a diagnostic device intended to be used to develop, fix, wash, and dry automatically and continuously film exposed for medical purposes. This is the sole purpose of this device.
Comparison Summary:	Unlike predicate devices which use rollers and gears to pull film through a series of open solution tanks, our processor holds film stationary in one processing tank. Furthermore, solutions are contained in 4 sealed reservoirs. Air pressure and vacuum forces the solutions up to the film, through a valve system. Film is never touched by a moving part, which is unlike other processors on the market. Developer temperature and time is controlled and adjusted automatically by a computer board. Maintenance is relatively low due to electronic draining; other processors require frequent manual cleaning and draining. Chemistry life is prolonged due to the sealed reservoirs, which also prevent the odors associated with open solution tanks. No plumbing is required, as it is in most predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 3 1999

Mr. Jim Jacobson
Owner
Dental X-ray Support Systems
2124-196th Street SW Suite B
Lynnwood, WA 98036

Re: K992896
DXSS Automatic X-ray Film Processor
Dated: August 24, 1999
Received: August 27, 1999
Regulatory Class: II (two)
Product Code: 90 EGY
21 CFR 892.1900

Dear Mr. Jacobson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992896

Device Name:_____

Indications For Use:

Device Name: *DXSS* Automatic X-ray Film Processor

Applicant: Dental X-ray Support Systems, Jim Jacobson

The *DXSS* Automatic X-ray Film Processor is an automatic radiographic film processor, a diagnostic device intended to be used to develop, fix, wash, and dry automatically and continuously film exposed for medical purposes. This is the sole purpose of this device.

(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, ENT,
and Radiological Devices
510(k) Number K992896

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)