

K974619

FEB 25 1998

510(k) Summary
for
ScanARay Advanced Computerized X-Ray System

1. **DATE SUMMARY PREPARED:** December 10, 1997

2. **SUBMITTER'S NAME AND ADDRESS**

AFP Imaging
250 Clearbrook Road
Elmsford, NY 10523

3. **CONTACT PERSON**

Mr. David Vozick

Telephone: (914) 592-6100

Facsimile: (914) 592-6148

4. **DEVICE NAME**

Trade/Proprietary Name: ScanARay/CD-Dent Advanced Computerized X-Ray System

Common Name: Electrostatic X-Ray imaging system (Dental)

Classification Name: Electrostatic X-Ray imaging system

5. **PREDICATE DEVICES**

The legally marketed devices to which equivalence is being claimed are:

- Digora marketed by Sorodex-finndent (K934949)
- DerOptix System marketed by Gendex (K955643)

6. **DEVICE DESCRIPTION**

The ScanARay Advanced Computerized X-Ray System is a filmless system intended for digital intraoral and extraoral radiography using a phosphor storage

screen. It enables the dentist to scan or import images for display, review or storage in a database. It consists of reusable phosphor storage screens for recording radiographic images, an image reader/digitizer, and software for displaying, enhancing, and storing dental radiographs using a user-provided personal computer.

7. INTENDED USE

The ScanARay Advanced Computerized X-Ray System is intended for digital dental radiography using a phosphor storage screen for radiographic diagnostic intraoral and extraoral exposures.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 25 1998

Mary M. McNamara-Cullinane, RAC
Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K974619
AFP Imaging ScanARay (CD-Dent) Advanced
Computerized X-Ray System
Dated: December 10, 1997
Received: December 11, 1997
Regulatory class: II
21 CFR 892.1630/Procode: 90 IXK/90 LMA

Dear Ms. McNamara-Cullinane:

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 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 requirement, 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/dsmamain.html>.

Sincerely yours,

Lillian Yin, Ph.D.
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): _____

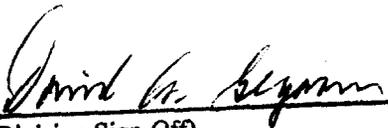
Device Name: _____

Indications For Use:

The ScanARay Advanced Computerized X-Ray System is intended for digital dental radiography using a phosphor storage screen for radiographic diagnostic intraoral and extraoral exposures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K974619

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)