

NOV 6 1998

**510(k) Summary  
for  
DXIS® Digital X-ray Imaging System**

510(k) # K983283

**1. SPONSOR**

Signet Radiology, Inc.  
253 Logue Rd.  
P.O. Box 508  
Minto, NB, E0E 1J0  
Canada

Contact person: Alex Cetateanu  
Telephone: (1)506-327-3931

Date prepared: September 4, 1998

**2. DEVICE NAME**

Proprietary Name: Signet DXIS® Direct X-ray Imaging System  
Common/Usual Name: Digital x-ray imaging system  
Classification Name: Extra-oral source x-ray system

**3. PREDICATE DEVICES**

Trophy Digipan (K961826)  
Siemens Orthophos DS (K972312)  
Planmeca Dimax (510(k) # not known)

**4. DEVICE DESCRIPTION**

The Signet DXIS® is intended for dental radiographic examination and diagnosis of the teeth, jaw, and oral structure.

The DXIS® System is designed to replace the film cassettes with a digital sensor in existing dental panoramic x-ray systems that are already on the market. It consists of a digital x-ray sensor, interface equipment, software, and adapters for specific dental x-ray systems. The DXIS® is installed by a Signet authorized technician on existing compatible dental x-ray systems. Software provided by Signet and a user supplied computer permit the images from the digital sensor to be recorded and displayed.

**5. INTENDED USE**

The Signet DXIS® is intended for dental radiographic examination and diagnosis of the teeth, jaw, and oral structure.

**6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIALLY EQUIVALENCE**

The DXIS®, like the predicate devices, provides the ability to display, store, or print digital radiographic images of the teeth, jaw or oral structure. A comparison of the DXIS® and the predicate devices is provided in the table given below.

**Comparison Table: DXIS® and predicate Devices**

	<b>Comparison</b>	<b>SIGNET Radiology</b>	<b>TROPHY</b>	<b>PLANMECA</b>	<b>SIEMENS</b>
1.	Trade Name	DXIS	DigiPan	Planmeca Dimax	Orthophos DS
2.	Panoramic Image	YES	YES	YES	YES
3.	X-Ray	YES	YES	YES	YES
4.	Replacement film cassette	YES	YES	YES	YES
5.	Digital processing	YES	YES	YES	YES
6.	Level of X-ray Radiation exposure	Up to 50%	70%	Information not available	Information not available
7.	Acquisition sensor	CCD DXIS Sensor	CCD Digital Cassette	CCD Digital	CCD Array
8.	Panoramic Acquisition Board	NO	YES	Information not available	Information not available
9.	Panoramic Correlator	YES	NO	Information not available	Information not available
10.	Computer Interface Board	YES	YES	YES	YES
11.	Acquisition Software	DXIS Acquisition Program	Trophy Windows Imaging (TWI)	Information not available	SIDEXIS
12.	Enhancement functions	YES	YES	YES	YES
13.	Digital storage	YES	YES	YES	YES
14.	Hard copy	YES	YES	YES	YES



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Alex Cetateanu  
President  
Signet Radiology, Inc.  
253 Logue Road  
P.O. Box 508  
Minto, NB, EOE 1J0  
CanadaRe: K983283  
Signet DIXS® Direct Dental X-ray Imaging System  
Dated: September 15, 1998  
Received: September 18, 1998  
Regulatory class: II  
21 CFR 872.1800/Procode: 90 MUH

Dear Mr. Cetateanu:

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 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/dsmarain.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): K983283

Device Name: DXIS®

Indications For Use:

THE DXIS® IS INTENDED FOR DENTAL RADIOGRAPHIC EXAMINATION AND  
DIOGNOSIS OF DISEASES OF THE TEETH, JAW AND ORAL STRUCTURE.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
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(Division Sign-Off) 4  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K983283

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over - The - Counter - Use \_\_\_\_\_