

K9 83267

DEC 30 1998

510 (k) Summary Statement for the Digora for Windows Dental imaging Software

I General Information

Submitter: Orion Corporation Soredex
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Contact Person: Kai Lanér, V. P.

Summary Preparation Date: September 10, 1998

Names

Proprietary Name: Digora for Windows 2.0

Common or Usual Name: Dental imaging software

Proposed Classification Name: System, Digital image communications

III Substantial Equivalent Devices

Digora for Windows 2.0 is substantially equivalent to Radworks Medical Imaging Software (K962699)

IV Product Description

Digora for Windows 2.0 is a dental imaging, image processing and archiving software, mainly to be used with Soredex Digora scanner (K934949). With this software it is possible to scan intra oral images using the Digora scanner, perform functions like edge enhancement, 3D emboss, density and contrast manipulation, length and angulation measurement with the image. The software also archives the images in the database, from where images can be stored in image media like CD-rom's.

V Intended Use of the Device

The Digora for Windows 2.0 is a software intended to using and managing dental x-ray images sent by Digora imaging plate scanner, storing the images and allowing the user to process and examine the images in order to achieve improved diagnoses. The software can also support other imaging devices such as larger size imaging plate scanners and intraoral video cameras.

VI Indications for Use/Rationale for Substantial Equivalence

"Digora for Windows 2.0" software is designed to carry out substantially equivalent imaging procedures as "RadWorks" software but the amount of them is much less and their complexity is much limited than with "Radworks". "RadWorks" is a general medical software which must be capable of satisfying the various needs of medical environment. "Digora for Windows 2.0" is a software used only with Soredex Digora scanners to scan, manipulate and archive the dental image.

VII Summary of technological characteristics

Digora for Windows 2.0 software is designed to

- scan images with Digora scanner
- import and export images
- allow images to be manipulated
 - 3D emboss
 - edge enhancement
 - length and angle measurement
 - zooming
 - density/contrast adjustment
 - colour effects
 - rotate images
 - positive/negative image
- store images in the database
- support video capture and store
- support external image media
- printing of images, image sets and patient list
- implant planning

VIII Safety and Effectiveness Information

Safety and effectiveness is demonstrated by:

- laboratory and clinical tests
- software verification, validation and certification procedures
- risk management file and risk management summary (IEC 601-1-4)

All the above items and evaluations lead to the conclusion that Digora for Windows 2.0 is safe and effective when the device is used as labelled.

IX Conclusion

Digora for Windows 2.0 Dental imaging software is substantially equivalent to the predicate device RadWorks, Medical imaging software.

The device has similar design ,operational and functional features as the current marketed predicative device.

The device has been shown to be safe and effective when it is used as labelled.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 30 1998

Kai Laner
V.P.
Orion Corporation Soredex
P.O. Box 79
FIN-00511 Helsinki
Finland

Re: K983267
Digora for Windows 2.0
Dated: November 16, 1998
Received: November 19, 1998
Regulatory class: II
21 CFR 872.1800/Procode: 90 MUH

Dear Mr. Laner:

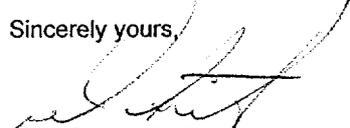
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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 :

DEVICE NAME :

DIGORA FOR WINDOWS 2.0

INDICATIONS FOR USE :

The Digora for Windows 2.0 is a software device intended to using and managing dental x-ray images sent by Digora imaging plate scanner, storing the images and allowing the user to process and examine the images in order to achieve improved diagnoses. The software can also support other imaging devices such as larger size imaging plate scanners and intraoral video cameras.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

[Handwritten Signature]
12/29/98

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use
(Optional Format 1-2-96)

[Handwritten Signature]
12/29/98

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K983267