

3/12/99

K990049

510(k) Summary  
for  
CD-Dent Digital-Imaging Device for Dental X-Ray Systems

**1. DATE SUMMARY PREPARED**

January 4, 1999

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

Digident Ltd.  
Yoqneam Star Bldg.  
Yoqneam  
P.O. Box 465  
Nesher 36603  
Israel

**3. CONTACT PERSON**

Mr. Betzalel Halevi  
Telephone: 011 972 4 959 1331  
Facsimile: 011 972 4 959 1262

**4. DEVICE NAME**

Trade/Proprietary Name: CD-Dent Digital Imaging Devices for Dental X-Ray Systems, Models 600, 1000, and 2000  
Common Name: Accessory to Electrostatic X-Ray imaging system (Dental)  
Classification Name: Accessory to Electrostatic X-Ray imaging system

**5. PREDICATE DEVICES**

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

- ScanARay Computerized X-Ray System marketed by AFP Imaging (K974619)

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

**6. DEVICE DESCRIPTION**

The CD-Dent Digital Imaging Devices for Dental X-Ray Systems are filmless systems intended for digital intraoral, extraoral and cephalometric radiography using a phosphor storage screen. They enable the dentist to scan or import images for display, review or storage in a database. They consist 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 CD-Dent Digital Imaging Devices for Dental X-Ray Systems are intended for digital dental radiography using a phosphor storage screen for radiographic diagnostic intraoral and extraoral images.



MAR 12 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K990049  
CD-Dent Digital-Imaging Devices for  
Dental X-Ray Systems  
Dated: January 6, 1999  
Received: January 7, 1999  
Regulatory class: II  
21 CFR 872.1800/Procode: 90 MUH

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 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): \_\_\_\_\_

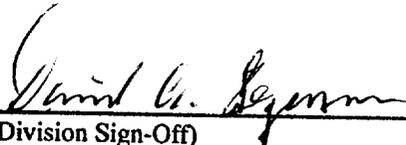
Device Name: \_\_\_\_\_

Indications For Use:

The CD-Dent Digital-Imaging Devices for Dental X-Ray Systems are intended for digital dental radiography using a phosphor storage screen for radiographicdiagnostic intraoral and extraoral images

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K990049

Prescription Use    
(Per 21 CFR 801.109)

OR

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

(Optional Format 1-2-96)