K042212

OCT 21 2004

510(k) Summary of Safety and Effectiveness (in accordance to 21 CFR 807.87(h))

Device Name

Proprietary Device Name : WBR -HR

Establishment Name and Registration Number of Submitter

Name: I-Dent Ltd.
Corresponding Official: Dan Laor
Yohanan 4, Box 6402
Hod Hasharon 45241, Israel

Device Classification

Classification Code:	90 LLZ
Regulation Number	892.2050
Common Name:	Picture Archiving and Communications System
Classification Class:	Class II Product

Reason for 510(k) Submission

Traditional 510(k) Submission

Identification of Legally Marketed Equivalent Devices

SimPlant system (K033847)

Device Description

The ImplantMaster system is a software interface used for the transfer of imaging information from a medical scanner such as a CT scanner, processing it and planning dental implant placement and surgical treatment. The ImplantMaster processes output result is used as an input data for CAD or Rapid Prototyping System.

Intended Use of Device

The ImplantMaster system is indicated for use as a front-end software interface for the transfer of imaging information from a medical scanner such as a CT scanner. It is also indicated for use as a planning and simulation software for use by qualified dental professionals to aid them in the placement of dental implants and surgical treatment. ImplantMaster processes the dental professional's input information and the result is used as an input data for CAD or Rapid Prototyping System.

Safety & Effectiveness

The device has been designed verified and validated complying to 21CFR 820.30 regulations. Bench and clinical data demonstrate that the implant placement positively match the planning. No adverse affects have been detected.

Substantial Equivalency

It is I-Dent's opinion that the ImplantMaster is substantially equivalent in terms of safety and effectiveness to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 21 2004

I-DENT
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K042212
Trade/Device Name: ImplantMaster
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: October 4, 2004
Received: October 6, 2004

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including. but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K042212

DEVICE NAME: ImplantMaster

INDICATION FOR USE: The ImplantMaster system is indicated for use as a front-end software interface for the transfer of imaging information from a medical scanner such as a CT scanner. It is also indicated for use as a planning and simulation software for use by qualified dental professionals to aid them in the placement of dental implants and surgical treatment. ImplantMaster processes the dental professional's input information and the result is used as an input data for CAD or Rapid Prototyping System.

(Please do not write below this line - continue on another page if needed)

(Concurrence of CDRH, Office of Device Evaluation (ODE))

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K042212

Prescription Use ✓ OR Over-the-Counter Use_____