

MAY - 9 2003

8.A 510(k) SUMMARY**(As required by Section 807.92(c))**

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Date Prepared: October 2002

Trade Name: IGI-System™

Classification: The FDA has classified "sterotaxic Instruments" devices as class II, pursuant to 21 C.F.R. § 882.4560 (product code HAW), and it is reviewed by the General & Plastic Surgery Advisory Committee.

Predicate Devices: Orthopilot, by Kinamed Inc. (K003347), and Vectorvision2, by BrainLab AG (K983831).

Description of the Device: The IGI-System is an electro-optical device, which was specifically designed to greatly improve the surgical implantation procedure by providing the surgeon an accurate guidance to the location of the surgical tools prior to, and more importantly, during the surgical operation.

The novel device both increases surgical success rate, and reduces potential damage to adjacent anatomical structures and tissues.

The IGI-System introduces, for the first time, the element of objective, state-of-the-art measurements to the field of dental implantation. Equipped with the IGI-System, the dental surgeon is able to plan the implantation procedure and align the actual placement of the implant in the pre-planned position with great accuracy.

The IGI-System allows the user to view the reconstructed 2D images of the patient anatomy together with overlaid graphic information depicting the position of dental surgical instrument and pre-planned position of dental implant.

The IGI-System utilises an infra-red (IR) optical tracking system, comprised of emitters, camera and a tracking data processor (computer), to determine the location and orientation of the dental hand-piece and the patient.

The position and orientation of both the dental surgical instrument and the patient are transmitted to an image data processor (computer) which makes necessary calculations to provide the guidance graphic overlay depicting the dental surgical instrument and planned dental implant location on the medical image.

Alignment of the patient and medical images is accomplished through a process termed fiducial registration. The goal is to indicate to the dentist, based on the pre-implantation medical images, the exact position of the tracked dental surgical instrument together with the location of planned dental implant location, with regard to the patient's anatomy.

The dentist will place a virtual implant image in the optimal location by use of the IGI software and available CT data. Once an implant has been optimally positioned, the

system will correlate between the dentist's plan and the actual performance. In case of significant variance between the plan and the performance the system will alert the user.

The system is used in two stages of the implantation procedure. The first stage is pre-planning of the surgical implantation procedure. The second stage is the clinical one in which the system is used for accurate guidance of dental surgical instruments according to the pre-planned implant position. In addition, the system assists the dentist in avoiding critical anatomical structures.

The system is used to pre-plan the surgical implantation procedure. Consequently, the system provides accurate guidance during the dental implantation, of surgical instruments with regard to pre-operative planning, and assists the dentist in avoiding the risk of causing damage to critical anatomical structures.

The IGI-System is defined as a supporting device, providing a significant contribution to the decision-making process, which continuously takes place during the implantation process. It is by no means intended to replace human judgement. The final decisions as to the exact location, timing, intensity and depth of the drilling are the sole responsibility of the surgeon.

The surgeon is at liberty, at any time throughout the surgical procedure, to determine the final drilling position, or to modify implants' planned position.

Thus, under no circumstances does the device relieve the surgeon of his or her ultimate clinical responsibility.

Intended Uses: The IGI Image-Guided Implantation system, is a computerized navigational system intended to provide assistance in both the planning (pre-operative) and the surgical (intra-operative) phases of dental implantation surgery. The system provides accurate navigational guidance of surgical instruments, with regard to the pre-operative planning in dental implantation procedure.

Substantial Equivalence: IGI-System shares technological and clinical features with two FDA-cleared tracking devices – The Orthopilot® (K003347) and the VectorVision® (K983831).

The Orthopilot® is a system for computer-aided navigation of surgical instruments, whose purpose is to optimally position the cutting guides for total knee replacement surgery and provided intra-operative measurements of bone alignment.

The VectorVision® (K983831) is an intra-operative image guided localization system to enable open or percutaneous surgery. It is indicated for any medical condition, where a reference to a rigid anatomical structure, such as the skull, a long bone or vertebra can be identified relative to a CT, MR or X-ray based model of anatomy.

The IGI-System and its two predicates share a principal feature - they provide their users with accurate guidance of surgical tools and/or implantable devices or organs. This guidance, achieved by the use of optical tracking of the surgical instruments, is an objective and accurate navigational guidance, used as an adjunct in implantation surgical procedures.

The devices are not intended to replace human assessment, but to provide objective information as to the positioning and alignment of the surgical instruments or implantable devices in reference to the patient's body.

The IGI-System and its two predicates share, in addition, several other significant features:

- All three devices are used as an aid for freehand operation by a surgeon.
- All three devices employ optical, infra-red light, tracking systems, for tracking, and two cameras for spatial reconstruction of instrument alignment and position.
- All three devices employ dedicated reconstruction software, intended to simultaneously visualize the anatomical structure of interest and the trajectory of the surgical instrument.
- All three devices reduce potential damage to adjacent anatomical structures.
- All three devices provide navigational accuracy of +/-0.5mm. This level of accuracy cannot be achieved by human visual inspection.

In addition, it is important to emphasize the similarities between the IGI-System and the VectorVision® (K983831). Both use CT scans as a reference for the determination of the exact positioning of the tools during the surgical procedure.

Also, although the VectorVision system is intended primarily for bone surgery, its intended use does indicate broader potential uses. Specifically, this device's

“Indications for Use” stipulates the use of this device “for any medical condition, where a reference to a rigid anatomical structure, such as the skull, a long bone or vertebra can be identified relative to a CT, MR or X-ray based model of anatomy”. Although the use of this device in dental implantation is not specifically noted, it is valid to envision dental CT scans a rigid spatial reference for navigation, as are the skull, long bones or vertebra. In this respect, dental use of a navigation tracking system is subsumed within VectorVision’s general indications for use, and is encompassed by the predicate device’s specific indications for use.

It is also significant to note that all three devices, the IGI-System and its two predicate devices, are intended to be used primarily on three different body organs.

The Orthopilot® (K003347) is a system for computer-aided navigation of surgical instruments, whose purpose is to optimally position the cutting guides for total knee replacement surgery and provided intra-operative measurements of bone alignment.

VectorVision® (K983831), as mentioned above, is an intra-operative image guided localization system to enable open or percutaneous surgery. It is indicated for any medical condition, where a reference to a rigid anatomical structure, such as the skull, a long bone or vertebra can be identified relative to a CT, MR or X-ray based model of anatomy.

However, as the effectiveness of all three devices is defined by the accuracy of the guidance they provide, the difference in body organs for which the three devices are intended affect neither their effectiveness, nor their safety, and does not raise any new question regarding the performance of these devices.

In summary, the IGI-System is substantially equivalent to its two cleared predicate devices in all its major characteristics.

Conclusions: Data presented above clearly demonstrate that the Image-Guided Implantation Device is substantially equivalent to its predicate devices in its technological features, clinical intended uses and its safety and effectiveness.

Performance Standards:

- EN 60601-1 1990 Medical electrical equipment. Part 1: General requirements for safety - IEC 601-1:1988
- Amendment A1 to EN 60601-1:1992 Medical electrical equipment. Part 1: General requirements for safety - IEC 601-1:1988/A1:1991

- Amendment A2 to EN 60601-1: 1995 Medical electrical equipment. Part 1: General requirements for safety - IEC 601-1:1988/A2:1995 + corrigendum June 1995
- Amendment A13 to EN 60601-1:1995 Medical electrical equipment. Part 1: General requirements for safety
- EN 60601-1-1 : 1993 Medical electrical equipment. Part 1: General requirements for safety - 1. Collateral standard: Safety requirements for medical electrical systems - IEC 601-1-1:1992
- Amendment A1 to EN 60601-1-1:1995 Medical electrical equipment . Part 1: General requirements for safety - 1. Collateral standard: Safety requirements for medical electrical systems IEC 601-1-1:1992/A1:1995
- EN 60601-1-2:1993 Medical electrical equipment - Part 1: General requirements for safety - 2. Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 601-1-2: 1993
- IEC 60601-1-4 :1996 Medical electrical equipment - Part 1: General requirements for safety - 4. Collateral standard: Programmable electrical medical systems
- EN 1041: 1998 Information supplied by the manufacturer with medical devices
- EN 1441: 1997 Medical devices - Risk analysis
- EN 980 /+A1: 1999 1996 Graphical symbols for use in the labeling of medical devices
- EN 540:1993 Clinical investigation of medical devices for humans

Accuracy and functional performance standard:

As of today, there are no specific FDA Guidance documents regarding the Image-Guided surgery systems for oral and maxillofacial surgery.

The level of accuracy, defined to be acceptable in dental implantation navigation, was +/-1mm. This level of accuracy was defined based on review of state of the art technology, opinions by experts in the field, and the accuracy specified for the FDA-cleared predicate devices (see Section 7).



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Food and Drug Administration
9200 Corporate Boulevard
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Denx Advanced Dental Systems
c/o Dr. Koby Ben-Barak
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Israel

Re: K023424
Trade/Device Name: IGI System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: April 6, 2003
Received: April 8, 2003

Dear Dr. Ben-Barak:

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 (PMA), 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 (301) 594-4659. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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,

for 
for Celia M. Witten, Ph.D., M.D.

Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K023424

8. C INDICATION FOR USE STATEMENT

The IGI-System™, Image-Guided Implantation System, is a computerized navigational system intended to provide assistance in both the planning (pre-operative) and the surgical (intra-operative) phases of dental implantation surgery. The system provides accurate navigational guidance of surgical instruments, with regard to the pre-operative planning in dental implantation procedure.

דנקס בע"מ
DENX LTD. *b*
ALON HAYKA

General Manager (Name & Signature)

8.10.2002
Date

(Premarket Notification [510(k)] Number)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023424