K061224

SEP - 5 2006

SECTION E - 510(k) SUMMARY

	Datum	Name
Erstellt	2006/04/04	
Geprüft	2006/04/24	
Genehmigt	2006/09/25	
Freigegeben	2006/09/25	

Section E - 510(k) Summary

Applicant's Name:
RoboDent GmbH
Kurfürstendamm 213
10719 Berlin
Tel: +49 (30) 49 500 820
Fax: +49 (30) 49 500 822

Contact Person :
Prof. Dr. mult. h.c. Jürgen Bier
RoboDent GmbH
Kurfürstendamm 213
10719 Berlin
Tel: +49 (30) 49 500 823
Fax: +49 (30) 49 500 822
j.bier@robodent.com

Date prepared : April 2006

Trade Name Lapdoc

Common name Image Guided Surgery System, CAS / Stereotaxic Instrument

Classification name Stereotaxic Instrument (per 21 CFR section 880.4560 HAW)

Regulatory Class: Class II

Predicate Devices:
IGI-System (K023424)
OrthoPilot (K003347)
Vectorvision Cranial / ENT (K023651)
Vectorvision^2 (K983831)

Classification: The FDA has classified "stereotaxic Instruments" devices as class II, pursuant to 21 CFR 882.4560 (product code: HAW).

Description of the Device: The Lapdoc System is a computer based assistance system for dental implantologists. It supports surgeons during planning and execution phase of dental implant procedures by providing highly precise guiding assistance during the implantation process within the human jaw. The systems supports the surgical implantation process by providing visual guidance for position and orienting of a dental bur relative to a planned implant position.

The Lapdoc system is designed to support clinicians by decreasing complication rates of surgical interventions in the field of dental implantology. Using the system will allow precise orientation of the surgeon within the human jaw both in the medical image model of the jaw during the planning phase as well as in real anatomy during the execution phase. This is achieved by objective measuring the spatial positions of surgical instruments and the patients anatomy. Based on three dimensional medical image data, the surgeon plans an intervention by virtually placing models of implants within the graphical depiction (of the medical image set) of the jaw. The surgeon views and interprets the medical images which are graphically augmented with the computer models of the implants. It is further possible to manually mark the outlines of sensitive anatomical structures (i.e. nerves) within

SECTION E - 510(k) SUMMARY

the medical images. To perfectly understand the geometric dimensions of the patients anatomy and the later intervention, a three dimensional model is created from isodense surfaces in the CT images and displayed on the computer screen. Lapdoc uses the geometric information of the planned implants within the medical images to generate highly precise information to guide the surgeon's instrument directly to the intended implant position and orientation.

An optical measurement system consisting of an infrared-based stereo camera system and a set of two rigid structures (also known as rigid bodies or trackers) with attached reflectors is used to measure the spatial positions of the patient and the instruments. Therefore, the trackers are reproducible attached to the patient (using a dental splint) and to the surgical bur (using a cone nut connector). The stereo camera system comprises an internal position measurement processor and is connected to the Lapdoc computer. It senses the positions of the instruments and the patients tracker and communicates it to the Lapdoc computer. The computer calculates in real time the deviation between the actual and the desired (from the planning phase) transformation of the positions of both trackers. The actual bur position and orientation and the planned implant position and orientation are graphically displayed to the surgeon using a mini-display. The mini-display is placed within the vicinity of the surgeon and near the patient's mouth. The surgeon minimizes this deviation during the drill procedure by moving the bur in a way, that position and orientation of both the dental bur and planned implant are congruent. The system supports the surgeon by achieving a highly precise surgical outcome according to the planned scenario.

Lapdoc system will graphically and audibly signal to the surgeon, if the plan is fulfilled and the surgical bur has reached its designated position and orientation. It will further warn the surgeon by reaching a minimal proximity value close to sensitive anatomical structures (i.e. nerves) and therefore avoids injury of such structures. Lapdoc is specifically designed to minimize the interaction between the user and the system. The application of the system follows simple ergonomic rules. The usage and working principle is easy to understand by the surgeon. The clinical workflow is not altered using Lapdoc.

To describe the patients anatomy and the medical image model in one common coordinate system, it is necessary to perform an image registration process. This registration process comprises a navigation bow of known geometry and an algorithm to detect and measure the position of the navigation bow within the medical image data set. Lapdoc correlates the positions of the navigation bow within the image data with its measured spatial position. Since the navigation bow is attached reproducible to the patients jaw by click-snaping it onto the patient's teeth, positions on or within the patients anatomy can also be described within the medical image data set using the registration function.

SECTION E - 510(k) SUMMARY

The Lapdoc provides accurate guidance during the process of dental implantation. Surgical instruments are guided according to a pre-operative planning. The surgeon is assisted by avoiding the risk of causing damage to critical anatomical structures. Lapdoc is defined as a clinical assistance system, to support the surgeon during the implantation process with the ability of precise determination of position and orientation of surgical instruments within the patients anatomy. Lapdoc does not replace the human judgment. It is always the surgeons choice to define specific locations and angulations of the implant and to pursue this decision within the clinical treatment phase. Thus, the surgeon will not be released from his/her sole and ultimate clinical responsibility.

Intended use: The Lapdoc navigation system is a computerized navigational system intended to provide assistance in the preoperative planning and the intra-operative surgical phases of dental implantation surgery. The system provides precise navigational guidance of surgical instruments such as a dental bur, according to the preoperative planning in the dental implantation procedure.

Substantial Equivalence: Lapdoc shares technological and clinical features and an identical *Intended use* with different FDA-cleared tracking devices. The *DenX-IGI (K023424)*, the *Orthopilot® (K003347)*, the *VectorVision Cranial / ENT ® (K023651)* and the *VectorVision 2 ® (K983831)* system. Together, all this devices share some important features (not exclusively):

- All devices serve as assistance systems by providing visual support during the freehand positioning and orientation process of surgical instruments relative to the patients anatomy;
- All devices measure positions of the human anatomy and surgical instruments by means of optical infrared-based measurement systems consisting of stereo camera systems;
- All devices calculate the position and orientation of surgical instruments within the medical image data set by using the position measurement data;
- All devices use sophisticated, yet easily understandable software tools to visualize medical image data in different manners (slices and three dimensional models) and the positions and orientation of surgical instruments;
- All devices reduce the risk of harming or damaging anatomical structures by visualization of such with respect to the actual positions of surgical tools;
- All devices provide navigational accuracy of +/- 1,0 mm (overall system accuracy), which can not be achieved by brut human visual inspection.

The *DenxIGI® (K023424)* system is a system for computer aided navigation of surgical instruments, whose purpose is to position a dental bur on the human jaw to optimally place and drill implant cavities. The system is based on the planning of such implant position and angulation within a three dimensional medical image data set (CT) and to pursue this position and angulation during the implantation process using an integrated position measurement device. The *Orthopilot®* (K003347) is

SECTION E - 510(k) SUMMARY

a computer aided system to navigate surgical instruments and to optimize the positions of cutting templates/guides for total knee replacement surgery and providing intra-operative measurements of bone alignment. The *VectorVision Cranial / ENT ® (K023651) and the VectorVision 2 ® (K983831)* are computer-aided systems for open or percutaneous surgery. They are 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.

Lapdoc and its predicate devices provide precise and accurate guidance of surgical tools and instruments within the patient's anatomy, near to organs or parts of it. Guidance is achieved by measuring positions of both the instruments and the anatomy and objective visualization of proportions and/or coherences of this spatial relationship.

All described devices do not intend to replace the surgeons expert knowledge and to release the clinicians responsibility.

The following navigation systems are used for the same body organs:

System	**organ / body part / clinical application**
DenX IGI® *(K023424)*	Navigation in dental implantology
Lapdoc	Navigation in dental implantology

Since the general principle of surgical navigation can be applied to any surgical field the following described navigation systems are used on different body organs:

System	**organ / body part / clinical application**
DenX IGI® *(K023424)*	Navigation in dental implantology
Orthopilot® *(K003347)*	Navigation for knee replacement surgery and bone alignment surgery
VectorVision 2 ® *(K983831)*	Navigation in open/percutaneous surgery (skull/long-bones/vertebraes)
VectorVision Cranial / ENT ® *(K023651)*	Navigation in open/percutaneous surgery (skull/long-bones/vertebraes)
Lapdoc	Navigation in dental implantology

The effectiveness of all navigation support systems is based on their accuracy during the actual spatial guiding process for surgical instruments. The underlying principles of measuring positions of parts of the human anatomy and the positions of instruments, the registration of medical image data to the anatomy does not change with respect to the specific field of application remain the same. It can be assumed, that the safety and performance assumptions are not altered, when the principle of navigation is applied to the field of dental navigation. Summarized, the LapDoc-system is substantially equivalent to the declared predicate devices.

SECTION E - 510(k) SUMMARY

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

Performance standards:

Standards No.	Standards Organization	Standards Title	Version	Date
601-1	IEC	Medical electrical equipment - Part 1: General requirements for safety	German version EN 60601-:1990 + A1:1993 + A2:1995	03/1996
60601-1-2	IEC	Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility Requirements and Tests.	German version EN 60601-1-2:2001	10/2002
60601-1-1	IEC	Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems	German version EN 60601-1-1:2001	08/2002
60601-1-4	IEC	Medical electrical equipment Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems	German version IEC 60601-1-4:1996+A1:1999	04/2001
60601-1/A13	EN	Medical electrical equipment - Part 1: General requirements for safety	German version EN 60601-1 :1990/ AM 13 :1996	10/1996
15223	ISO	Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied	2nd edition	04/2000
10993-5	ISO	Biological Evaluation of medical devices Part 5: Tests for cytotoxicity: in-vitro methods	German Version EN ISO 10993-5:1999	11/1999
10993-10	ISO	Biological Evaluation of medical devices Part 10: Tests for irritation and delayed-type hypersensitivity	German version EN ISO 10993-10:2002	02/2003
14791	ISO	Medical devices – Application of risk management to medical devices	German version EN ISO 14971:2001	03/2001
980	EN	Graphical symbols for use in the labelling of medical devices	German version EN 980:2003	08/2003
1041	EN	Information supplied by the manufacturer with medical devices	German version EN 1041:1998	04/1998
F899	ASTM	Standard Specification for Stainless Steel for Surgical Instruments	02	04/2002
A182	ASTM	Forged or Rolled Alloy and Stainless Steel Pipe Flanges, Forged Fittings, and Valves and Parts for High-Temperature Service	04	10/2004
B265	ASTM	Standard Specification for Titanium and Titanium Alloy Strip	03	11/2003
F67	ASTM	Standard Specification for unalloyed Titanium for surgical Implant Applications	00	10/2000

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 +/- 1,0 mm. This level of accuracy was defined based on review of state of the art technology (see Appendix documents No. 8 to No. 12), opinions by experts in the field (see Appendix documents No. 6 to No. 8) and the accuracy specified for the FDA cleared predicate devices (see Appendix documents No. 13 to No. 16).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2006

Robodent GMBH
% Mr. Juergen Bier
Kurfurstendamm 213
Berlin, Germany 10719

Re: K061224
Trade/Device Name: Lapdoc
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulation Class: Class II
Product Code: HAW
Dated: August 14, 2006
Received: August 21, 2006

Dear Mr. Bier:

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 (240) 276-0115. 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 from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K061224

Device Name: Lapdoc

Indications For Use:
The Lapdoc navigation system is a computerized navigational system intended to provide assistance in both the preoperative planning and the intra-operative surgical phases of dental implantation surgery. The system provides precise navigational guidance of surgical instruments such as a dental bur, with regard to the pre-operative planning in the dental implantation procedure.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061224/S1