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K071636

5. 510(k) Summary of Safety and Effectiveness

AUG - 9 2007

5.1. Submitter

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5.2. Official Correspondent

Mr. Frank Stockmann, Chief Executive Officer
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5.3. Date of submission

05/24/2007

5.4. Device Information

Trade name:	*coDiagnostiX*®
Version:	5.7.2
Common Name:	Dental 3D diagnosis and implant planning software
Device Class:	Class II
Classification name:	Image Processing System
Classification Panel:	Radiology
Classification number:	21 CFR 892.2050
Product Code:	LLZ

5.5. Predicate Device(s)

	Predicate #1	Predicate #2
Manufacturer	MATERIALIZE N.V.	CyberMed, Inc.
Trade Name	SimPlant System	Vimplant™
510(k) Number	K033849	K053155
Regulation Number	892.2050	892.2050
Product Code	LLZ	LLZ

5.6. Device Description

coDiagnostiX® is designed for diagnosis of 3dimensional datasets and precise image- guided and reproducible pre- operative planning of dental implants.
The software will be provided either as station version, client or server version.
Basically, patient's medical image data from different sources like CT (computer tomography) - or DVT (Digital Volume Tomography resp. NewTom) scanner will be read in with the *coDiagnostiX®* DICOM transfer module, transferred into 3dimensional datasets and stored in a database.
The succeeded planning is realized through the calculation of special views, the analysis of graphic data and the placement of dental implants. For assistance of the planning procedure, several functions are available:

- Active measurement tools (length and angle) for individual measuring of implant positions
- Nerve module for distinguishing the behaviour of the nervus mandibularis channel
- 3D Cut for a 3dimensional cut through the jaw for fine adjustment of the implant position
- Segmentation module for coloring several areas inside the slice dataset (e.g. jaw bone, natural tooth series) or kinds of tissue (e.g. bone, skin) and creating a 3D reconstruction of the dataset
- Parallelizing function for adjustment of adjacent images
- Bone densitometry with a density statistic for density measuring in the area around the positioned implant; a density allocation along the and transverse to the implant cover area is displayed

All working steps will be saved automatically to the actual plan of the patient. For each patient several plans are possible to generate several proposals, so that the dentist or lab is free to choose the ideal proposal for generating an according drilling template needed for realization of the planning during the main operation.
As in the station version of the *coDiagnostiX®* software all functions are available, the client version needs the patient data provided by the server version.

5.7. Intended Use

coDiagnostiX® is intended for use by medical trained people as a Windows®- based diagnosis and implant planning software.
This software is an interface for the transfer of imaging information from medical scanners such as CT or DVT scanners and also a pre- operative software for simulation and evaluation dental implant placement and surgical treatment options.
The patient population will be the general public.
coDiagnostiX® is not intended to be used in direct contact with the patient nor is it intended to be used with life sustaining devices.
It's possible to use *coDiagnostiX®* as a pattern for manufacturing drilling templates with conventional rotary tables or the gonyX® table from IVS Solutions AG in laboratory environment. This drilling template is then used in direct contact with the patient to realize the implant planning with *coDiagnostiX®*.

5.8. Applicable mandatory and voluntary standards

coDiagnostiX® complies with the following mandatory and voluntary standards:

- ISO 9001:2000 - Quality management systems
- ISO 13485:2003 - Quality management systems, requirements for regulatory purposes
- ISO 14971:2001 - Application of risk management to medical devices
- IEC 60601-1-4:1996 + A1:1999 Medical electrical equipment - Part 1-4: General requirements for safety; Collateral standard: Programmable electrical medical systems

- 93/42/EEC - Medical Device Directive
- DICOM (Digital Imaging and Communications in Medicine) -
  The standard protocol to exchange and transfer the data acquired by Medical Image Devices; developed by the American College of Radiology and the National Electrical Manufacturers Association (ACR- NEMA).
- JPG/ JPEG (Joint Photographic Experts Group) -
  A compression technique that is designed to compress color and greyscale continuous- tone images reversible and irreversible.

5.9. Technological Characteristics

coDiagnostiX® is a dental image diagnosis and implant planning software, designed to run on industrial standard PC platforms with the following minimum system requirements:

- WIN 98/NT/2000/XP
- Pentium compatible Processor with 800MHz
- 128 MB RAM
- 500 MB hard disc
- 17" color display with 1024x768 resolution and 16.7 Million colors
- CD- ROM device
- USB interface.

The software will be delivered on CD with a hardware copy protection (eToken- Dongle). If the user wants to work with *coDiagnostiX®*, the Dongle has to be connected to the PC via USB interface.
In addition *coDiagnostiX®* is designed for:

- utilization of the DICOM 3.0 standard to acquire images from network or CD- ROM
- supporting standard image file formats for storage and retrieval of images (DICOM, JPEG, BMP, TIFF)
- importing and exporting images
- 3D image reconstruction
- image- guided implant planning
- nerve creation and displaying
- collision detection
- printing images, image sets, implant list, drilling template plan

5.10. Safety Information

coDiagnostX® is a software product that handles digital medical images. The device does not contact the patient, nor does it control any life sustaining devices.
All potential hazards have been studied and controlled as part of the product development process according to written procedures, including risk analysis, test and design considerations, verification and validation testing processes. The results of the hazard analysis indicate that the device is of moderate level of concern as per "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

5.11. Conclusion

coDiagnostiX® has similar intended use, operational and functional features as the predicate devices. Any differences between the devices do not raise new issues of safety and effectiveness. That indicates, that *coDiagnostiX®* is substantially equivalent to and performs as good as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

AUG - 9 2007

Mr. Frank Stockmann
Chief Executive Officer
IVS Solutions AG
Annaberger Strasse 240
Chemnitz, Saxony 09125
GERMANY

Re: K071636
Trade/Device Name: coDiagnostix®
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 24, 2007
Received: June 15, 2007

Dear Mr. Stockmann:

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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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,

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

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4. Indications for Use Statement

510(k) Number (if known): K071636

Device Name: *coDiagnostiX®*

Indications for Use:

coDiagnostiX® is intended for use by medical trained people as a Windows®- based diagnosis and implant planning software.
This software is an interface for the transfer of imaging information from medical scanners such as CT or DVT scanners and also a pre- operative software for simulation and evaluation dental implant placement and surgical treatment options.
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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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K071636