510K Summary K113404

DEC - 6 2011

Device Owner	Symbyo Dental, LLC.
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Device Name and Classification

Trade Name/Product Name:	IPS
Common/Usual Name:	Dental 3D Planning Software
Classification Name:	System, Image Processing, Radiological; 21CFR892.2050
Product Code:	LLZ
Regulation Number:	Picture Archiving and Communication System, 21CFR892.2050
Panel:	Radiology
Class	2
Substantial Equivalence claimed to:	MATERIALISE N.V. Simplant system (K033849) siCAT GmbH & Co. KG Sicat implant (K090119)

Device Description

IPS is a Dental 3D Planning Software that aids dentists and dental lab technicians in the creation of 3D models of oral maxillofacial region and in planning dental surgical treatments and placement of dental implants. The data used for planning the treatment course is obtained from radiological devices (e.g., CT) complying with DICOM format. IPS provides dentists with various visualization and measurement tools which facilitate in generating dental panoramic view, segmenting of the dental anatomical structures and measuring bone density and distance between the dental implants.

Indications for Use

IPS is prescription use software used by dentists and dental lab technicians for the visualization and image segmentation of DICOM data from medical scanners such as CT. The software aids the user in the creation of 3D models of oral maxillofacial region and in planning dental surgical treatments and placement of dental implants.

Substantial Equivalence

Symbyo Dental LLC. wishes to use the following devices as a predicates:

MATERIALISE N.V. Simplant system (K033849)
siCAT GmbH & Co. KG Sicat implant (K090119)

The claim of substantial equivalence to the predicate devices is based on both intended use and technology used.

Areas of Comparison	**Simplant system K033849**	**Sicat implant K090119**	**IPS**
Description	Pure software device	Pure software device	Pure software device
Input source	CT scanners , MRI machines	CT scanners , DVT scanners	Cone beam CT machines ,CT scanners
Data conformance	DICOM	DICOM	DICOM
Regulation description	Picture archiving and communication system	Picture archiving and communication system	Picture archiving and communication system
Intended use	Visualization and planning simulation that aids the user in the placement of dental implants and planning for surgical treatments	Visualization and planning simulation that aids the user in the placement of dental implants and planning for surgical treatments	Visualization and planning simulation that aids the user in the placement of dental implants and planning for surgical treatments
Intended user	Well trained dentist \ dental technicians	Well trained dentist	Dentists, dental technician
Main tools	Visualization , implant placement , measurement of distance ,angle measurement , density determination , segmentation tool	Visualization , implant placement , measurement of distance ,angle measurement , density determination	Visualization , implant and nerve placement , measurement of distance ,angle measurement , density determination , segmentation tool
Host platform	PC	PC	PC
Operating system	Not specified	Not specified	Windows XP , vista , 7
Output compatibility	CAD , rapid prototyping machines	CAD , rapid prototyping machines	CAD , rapid prototyping machines
Operating system compatibility	- Windows XP or vista - Intel based MAC (computer should be booted from windows not MAC OS)	- Windows XP - Windows Vista - WINDOWS 7	- Windows XP - Windows Vista - WINDOWS 7

Predicate Comparison Table

Based Upon Intended Used:

IPS and its predicate devices have the same intended use; which is Visualization and planning simulation that aids the user in the placement of dental implants and planning for dental surgical treatment.

Based Upon Technology Used:

IPS, like the predicate devices, is a pure software device with DICOM data conformance.

The technological characteristics of IPS vs. the predicate devices are summarized below.

Our software conforms to DICOM standard and it has been verified and validated for it.

Validation and verification was performed to demonstrate DICOM conformance

Following test cases were used to validate DICOM conformance:

- Importing DICOM Data.
- Sorting DICOM data.
- Grouping multiple DICOM case

These test cases have been adopted to perform a validation process according to the IPS DICOM Conformance statement. These test cases are performed on the patient's DICOM images to ensure that the IPS application's modules are fully compliant with the DICOM conformance.

Conclusion
The results of all testing demonstrate that IPS does not raise any new issues of safety, effectiveness or performance when compared to the existing predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Symbyo Dental, LLC.
% Mr. Mark Job
Official Correspondent
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DEC - 6 2011

Re: K113404
Trade/Device Name: Dental 3D Planning Software IPS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 17, 2011
Received: November 18, 2011

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Device Name: Dental 3D Planning Software IPS

Indications for Use:

IPS is prescription use software used by dentists and dental lab technicians for the visualization and image segmentation of DICOM data from medical scanners such as CT. The software aids the user in the creation of 3D models of oral maxillofacial region and in planning dental surgical treatments and placement of dental implants.

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K113404