MAR 4 2009

Summary

This 510(k) Summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared January 29, 2009.

Company 21 CFR 807.92(a)(1):

Visual Medical Solutions
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Ames, IA 50010

Curt Carlson, President
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Contact :

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Delphi Consulting Group
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Trade Name, Common Name and Classification 21 CFR 807.92(a)(2):

Trade Name:	**BodyViz**
Common Name:	**Picture Archiving Communications System**
Device Classification:	**892.2050 LLZ**

Predicate Device 21 CFR 807.92(a)(3)

K072653, 3viseon/surgery™ and K082041, Fiatlux Visualize

Device Description 21 CFR 807.92(a)(4):

BodyViz is a software based application for creating 3D models of patient data from 2D scan slices. Users have the ability input, display, color, and manipulate the 2D scan slices via a 3D representation. BodyViz is a visualization environment that allows surgeons to plan various types of surgery on their patient data in 3D.

BodyViz works with any DICOM formatted 2D image scan slices. Data can be accessed from internal and external data storage devices, as well as network and CD/DVD data sources. The software runs on any modern Windows based

computer (i.e. laptop or desktop) with a 3D graphics card that meets minimum requirements, eliminating the need for specialized hardware.

BodyViz is a medical device image software that is used with computer hardware in a typical hospital or clinic networked computer environment. The device does not contact the patient, nor does it control any life sustaining devices. A physician, providing sufficient opportunity for competent human intervention, interprets images and information being displayed.

Indications for Use 21 CFR 807.92(a)(5):

BodyViz is a software device that receives digital images and data from various sources (i.e. CT scanner, MRI scanners). Data must be in DICOM format. Images and data are parsed, stored, processed, and displayed within the system as 3D representations. Image tools are available such as translation, rotation, scaling, clipping, and coloring. A data tool is available to window the displayed representation to certain tissue types based on tissue density (e.g., muscle, bone, or skin). Analysis of images and diagnosis is not performed by the software but by physicians or trained professionals.

Technological Characteristics 21 CFR 807.92(a)(6):

BodyViz Software System is medical device image software that is used with acceptable computer hardware in a picture archiving and communications system user environment. The device does not contact the patient, nor does it control any life sustaining abilities.

Testing:

BodyViz software has been tested to DICOM media storage application profiles.

Conclusion:

The 510(k) Pre-Market Notification BodyViz contains adequate information and data to enable the FDA – CDRH to determine substantial equivalence to the predicate device.

The submission contains the results of a hazard analysis and the "Level of Concern" for potential hazards has been classified as "minor."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 4 2009

Visual Medical Solutions, LLC
% Mr. J. Harvey Knauss
Consultant
Delphi Consulting Group
11874 South Evelyn Cricle
HOUSTON TX 77071

Re: K090295
Trade/Device Name: BodyViz Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 3, 2009
Received: February 5, 2009

Dear Mr. Knauss

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 os 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 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, 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.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K090295

Device Name: BodyViz Software

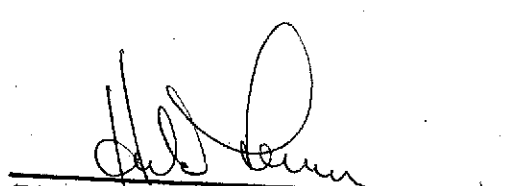
INDICATIONS FOR USE:

BodyViz is a software device that receives digital images and data from various sources (i.e. CT scanner, MRI scanners). Data must be in DICOM format. Images and data are parsed, stored, processed, and displayed within the system as 3D representations. Image tools are available such as translation, rotation, scaling, clipping, and coloring. A data tool is available to window the displayed representation to certain tissue types based on tissue density (e.g., muscle, bone, or skin). Analysis of images and diagnosis is not performed by the software but by physicians or trained professionals.

Prescription Use **YES** (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use (21 CFR 807 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 Reproductive, Abdominal, and Radiological Devices
510(k) Number K090295