K094064

Premarket Notification (510(k)) Summary

1. **Sponsor Information**

3M IMTEC

2401 North Commerce

Ardmore, OK 73401

APR 30 2010

Contact Person: Ginger Cantor, RAC

Regulatory Affairs Specialist

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Date of Summary: December 29, 2009

2. **Device Name and Classification:**

Common or Usual Name:	Software application for medical purposes (diagnostic imaging)
Proprietary Name:	ILUMAVision, v. 2.2
Classification Name:	Picture Archiving and Communications System, Class II device, 21 CFR §892.2050
Performance Standards:	None

3. **Predicate Device:**

ILUMAVision, version 2.0 (K081347)

4. Description of Device:

ILUMAVision is an image management software application used for the display and 3D visualization of medical image files obtained from scanning devices, such as computed tomography (CT), magnetic resonance imaging (MRI), positron emission tomography (PET) or three-dimensional (3D) ultrasound.

ILUMAVision uses image filtering, 3D reconstruction and quantitative algorithms to view, measure, and annotate images. ILUMAVision can be used to make panoramic images and to monitor treatment progress, capture images, bookmark certain items in a treatment, generate and edit reports, and export datasets. The application can also query and import images directly from a Picture Archiving and Communication System (PACS) over a TCP/IP network.

It distributes DICOM 3.0 compliant images, using standard personal computer (PC) hardware. Images can also be saved in JPEG format.

The software is intended to run on a personal computer (PC).

5. Intended Use/Indications for Use:

ILUMAVision is a software application used for the display and 3D visualization of medical image files from scanning devices, such as CT, MRI, PET or 3D Ultrasound.

It is intended for use by radiologists, clinicians, referring physicians and other qualified individuals to retrieve, process, render, review, store, print, and distribute DICOM 3.0 compliant images, utilizing standard PC hardware.

Additionally, ILUMAVision is a preoperative software application used for the simulation and evaluation of dental implants, orthodontic planning and surgical treatments.

ILUMAVision is not intended for use with mammography.

6. Substantial Equivalent Determination

Version 2.2 includes additional features of a temporal bone module, a virtual endoscope module and the functionality of exporting directly from the application

The additional software features have been suitably verified and validated; the table below identifies the equivalence between the modified ILUMAVision software (v. 2.2) and the cleared predicate ILUMAVision software (v. 2.0).

While new features have been added, ILUMAVision version 2.2 as modified in this pre-market notification submission has the same intended use, same intended users and indications for use as the predicate device ILUMAVision version 2.0.

Substantial Equivalence Summary Table			
Feature	**ILUMAVision version 2.0 (Predicate- K081347))**	**ILUMAVision version 2.2 (This submission)**	**Comment**
Indications for Use	A software application used for the display and 3D visualization of medical image files from scanning devices, such as CT, MRI, PET or 3D Ultrasound. Intended for use by radiologists, clinicians, referring physicians and other qualified individuals to retrieve, process, render, review, store, print, and distribute DICOM 3.0 compliant images, utilizing standard PC hardware. Additionally, ILUMAVision is a preoperative software application used for the simulation and evaluation of dental implants, orthodontic planning and surgical treatments. ILUMAVision is not intended for use with mammography.	A software application used for the display and 3D visualization of medical image files from scanning devices, such as CT, MRI, PET or 3D Ultrasound. Intended for use by radiologists, clinicians, referring physicians and other qualified individuals to retrieve, process, render, review, store, print, and distribute DICOM 3.0 compliant images, utilizing standard PC hardware. Additionally, ILUMAVision is a preoperative software application used for the simulation and evaluation of dental implants, orthodontic planning and surgical treatments. ILUMAVision is not intended for use with mammography.	No change from original 510(k)
Computer Platform	Minimum Requirement: Intel®-based PC running Microsoft® Windows®	Minimum Requirement: Intel®-based PC running Microsoft® Windows®	No change from original 510(k)
Communications	TCP/IP	TCP/IP	No change from original 510(k)
DICOM Compliance	DICOM 3.0	DICOM 3.0	No change from original 510(k)
JPEG Compliance	Images may be saved in JPEG format	Images may be saved in JPEG format	No change from original 510(k)
Input Image Format	DICOM 3.0	DICOM 3.0	No change from original 510(k)
Output Image Format	DICOM 3.0	DICOM 3.0	No change from original 510(k)
Image Archive	Computer hard drive, CD, DVD	Computer hard drive, CD, DVD or PACS	Added PACS capability to archiving
Image Display	Color/Grayscale CRT or LCD	Color/Grayscale CRT or LCD	No change from original 510(k)

Substantial Equivalence Summary Table			
Feature	**ILUMAVision version 2.0 (Predicate- K081347))**	**ILUMAVision version 2.2 (This submission)**	**Comment**
Printing	Print to standard PC connected printers	Print to standard PC connected printers	No change from original 510(k)
Import from PACS	Not in original 510k	New functionality	New feature
Export to PACS	Not in original 510k	New functionality	New feature
Volume Rendering	Radiographic Projection, Surface rendering, Fly-through	Radiographic Projection, Surface rendering, Fly-through	No change from original 510(k)
Image Edit	Multi-tissue opacity control, volume sculpting, segmentation	Multi-tissue opacity control, volume sculpting, segmentation	No change from original 510(k)
Region of Interest (ROI)/Volume of Interest (VOI)	2D region and 3D volume of interest selection tools	2D region and 3D volume of interest selection tools	No change from original 510(k)
2D Measurements	2D measurement tools including distance and angle	2D measurement tools including distance and angle	No change from original 510(k)
3D Measurements	3D measurement tools including distance and angle	3D measurement tools including distance and angle	No change from original 510(k)
Implant Planning	Tools for pre-surgical planning of dental implant placement	Tools for pre-surgical planning of dental implant placement	No change from original 510(k)
Stent Fabrication	Tools for pre-surgical fabrication of stents to aid dental implant insertion	Not a current feature- **Note:** Feature was never incorporated into final release of original cleared ILUMAVision, version 2.0	No change from original 510(k)
Orthodontic Treatment Planning	Tools for planning orthodontic treatment	Tools for planning orthodontic treatment	No change from original 510k
Temporal Bone Module	This module is used to isolate and examine the temporal bone	New feature- not in original 510(k)	New feature
Endoscope Module	This module allows the user to perform a virtual endoscopy	New feature – not in original 510(k)	New feature

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

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APR 30 2010

Re: K094064
Trade/Device Name: ILUMA Vision (Version 2.2)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 29, 2009
Received: December 31, 2009

Dear Ms. Cantor:

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,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K094064

Device Name: ILUMAVision (Version 2.2)

Indications for Use:

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ILUMAVision is not intended for use with mammography.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K094064