K030635

MAR 2 8 2003

OBSIDIAN
MEDICAL TECHNOLOGY

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510(k) Summary of Safety and Effectiveness

Date Prepared:
April 22, 2002

Submitter's Information: 21 CFR 807.92(a)(1)
Obsidian Medical Technology, Inc.
Contact: Bianca Green
5108 Corona Court
Pleasanton, CA 94588
Tel: (925) 426-3111
Fax: (925) 426-3001

Trade name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	The Obsidian PACS System
Common Name:	Picture Archiving Communications System
Device Classification:	892.2050
Name:	System, Image Processing, Radiology

Predicate Device: 21 CFR 892.92(a)(3)

Manufacturer:	Echo Tech 3D Imaging Systems, Inc.
Device:	Echo Tech Easy 3D
510(k) Number:	K013088
Date Received:	03/06/2002
Decision Date:	04/04/2002
Decision:	Substantially Equivalent
Panel Code device reviewed by:	Radiology
Panel Code device classified by:	Radiology
Product Code:	LLZ
Classification:	Class II – 892.2050

Device Description: 21 CFR 807 92(a)(4)

The Obsidian PACS System is comprised of components that connect to an analog or digital medical imaging device (ultrasound, CT, MRI, digitizer), transmit image or patient data, and store image or patient data. The transmission of data can occur internally or externally using a local area network or Internet connection.

Indications for Use: 21 CFR 807 92(a)(5)

The Obsidian PACS System is used to acquire, transmit, view, and store image or patient data. This data can be transmitted, stored, and viewed over a computer network or off-site using an Internet connection. The typical users of this system are trained professionals, including but not limited to, radiologist, physicians, technicians, and nurses.

The 3D Ultrasound Image Router is indicated for capture and storage of 2D images from an ultrasound system and reconstructing them into 3D ultrasound images. These images provide an approximate representation of the 3D volume for use in obstetric exams. The 3D images are not intended for use in diagnosis or quantitative measurements. This device is intended to provide an approximate representation of the 3D volume for use in obstetric exams.

Technological Characteristics: 21 CFR 807 92(a)(6)

The device does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed. This device transmits data on and off-site.

Conclusion: 21 CFR 807 92(b)(3)

In accordance with the FDA document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," the level of risk of the Obsidian PACS System was considered to be **minor**. The documentation submitted on the device system reflects this level of risk and consist of the following documents:

- Architectural design chart
- Hazard analysis
- DICOM conformance statement

These documents contain adequate information and data to enable FDA – CDRH to determine substantial equivalence to the predicate device. The Obsidian PACS System will be manufactured in accordance with the standards listed in the enclosed specifications documentation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 8 2003

Obsidian Medical Technology, Inc.
% Ms. Laura Danielson
510(k) Program Manager
TÜV Product Service
1775 Old Highway 8 NW, Suite 104
NEW BRIGHTON MN 55112-1891

Re: K030635
Trade/Device Name: Obsidian PACS System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: March 18, 2003
Received: March 20, 2003

Dear Ms. Danielson:

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 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

INDICATIONS FOR USE

510(k) Number (if known): K030635

Device Name: The Obsidian PACS System

Indications for Use:
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Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030635