K083691



# XII. 510(k) SUMMARY

FEB 25 2009

This 510(K) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

**Submitter's Information:**

Manufacturer: MicroMRI, Inc.
580 Middletown Boulevard
Suite D-150
Langhorne, PA 19047

Contact: Richard Elrath
Manager Quality Assurance and Regulatory Affairs
MicroMRI, Inc.
Phone: 267 212-1119
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**Trade Name, Common Name and Classification:**

Trade Name: BoneVue
Common Names: Image processing software
Classification Name: System, Image Processing, Radiological
Product Code: LLZ

**Predicate Devices:**

| 510k Reference No. & Date | Device Name | Manufacturer |
|---|---|---|
| K070831<br>May 22, 2007 | Voxar 3D™ | Barco View MIS<br>2 Anderson Place<br>Edingburgh, EH6 5NP,<br>UK |
| K011142<br>May 8, 2001 | Aquarius Workstation™ | TeraRecon, Inc.<br>2955 Campus Drive,<br>Suite 325<br>San Mateo, CA 94403 |
| K053281<br>September 3, 2004 | EVMS™ Enterprise<br>Visual Medical System | Emageon UV, Inc.<br>131 Wilson Street<br>Suite 700<br>Madison, WI 53703 |
| K071331<br>May 25, 2007 | Vitrea ® Version 4.0<br>Medical Image<br>Processing Software | Vital Images, Inc.<br>5850 Opus Parkway,<br>Suite 300<br>Minnetonka, MN 55343 |

**Device Description:**

BoneVue evaluates high-resolution MRI datasets containing bone tissue and provides 3D visualization of trabecular structures as well as measurements of descriptive parameters regarding cortical and trabecular morphology.

The following cortical measurements are reported: average cortical inner diameter, average cortical outer diameter, and average cortical thickness.

The following trabecular measurements are reported: average measures of bone volume/total volume, trabecular thickness, trabecular number, and trabecular separation.

The 3D visualization module is used to display a high resolution 3D model of the trabecular bone and its micro-architecture. The 3D visualization helps a trained physician make a qualitative assessment of bone micro-architecture, which may be viewed from different angles. BoneVue allows standard surface rendering views as well as standard maximum intensity projection views.

Additionally, BoneVue offers the display of a standard "bone plug", a surface rendering of a central cylinder of trabecular tissue, as a representative sample of the bone micro-architecture.

**Indications for Use:**

BoneVue is a software tool for 3D visualization of bone micro-architecture using MRI datasets with the possibility of manual or automated measurements of descriptive parameters regarding cortical and trabecular morphology. BoneVue is a workflow tool intended to assist a trained physician in the assessment of high-resolution MRI datasets of bone.

**Technological Characteristics**:

BoneVue software does not control image acquisition and can be used with a variety of commercially available pulse sequences and imaging coils. BoneVue does not contact the patient, nor does it control any life sustaining devices. A trained physician interprets the data and information being displayed.

**Performance Testing:**

BoneVue has been successfully tested and has met acceptance criteria previously established in accordance with documented procedures.

**Conclusion:**

The 510(k) Pre-Market Notification contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate devices. BoneVue has been developed, and will be manufactured in accordance with the MicroMRI's established Quality Policy Manual, which meets all of the requirements of 21 CFR Part 820, Quality System Regulation and ISO 13485, Medical Devices – Quality Management Systems – Requirements for regulatory purposes. 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

FEB 2 5 2009

Mr. Richard Elrath
Manager of Quality Assurance and Regulatory Affairs
MicroMRI, Inc.
580 Middletown Boulevard, Suite D-150
LANGHORNE PA 19047

Re: K083691
Trade/Device Name: BoneVue
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 8, 2008
Received: December 15, 2008

Dear Mr. Elrath:

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

# XIII. STATEMENT of INDICATIONS FOR USE

## Indications for Use

510(k) Number (if known): ~~N/A~~ K083691

Device Name: BoneVue

Indications for Use:

BoneVue is a software tool for 3D visualization of bone micro-architecture using MRI datasets with the possibility of manual or automated measurements of descriptive parameters regarding cortical and trabecular morphology. BoneVue is a workflow tool intended to assist a trained physician in the assessment of high-resolution MRI datasets of bone.

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 K083691