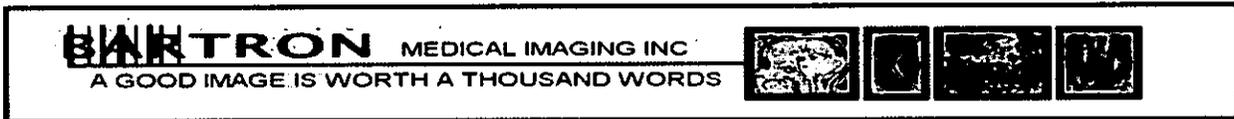


K092328
P. 1 of 2



510 (k) SUMMARY

Bartron Medical Imaging MED-SEG™ System

JUL 26 2010

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

Manufacturer: Bartron Medical Imaging, Inc.
1100 Mercantile Lane, Ste 115A
Largo, MD 20774
Telephone: (301) 583-4642 /x243
Facsimile: (301) 772-8540

Contact Person: Zvi Ladin, PhD.
Principal
Boston MedTech Advisors, Inc.
990 Washington Street
Suite #204
Dedham, MA 02026
Telephone: (781) 407 0900 x104
Facsimile: (781) 407 0901
Email: zladin@bmtadvisors.com

Date Prepared: July 12, 2010

Name of Device and Name/Address of Sponsor

Trade/Proprietary Name: MED-SEG™
Common Name: Picture Archiving and Communication System
Classification Name: System, Image Processing, Radiological
Regulatory Class: II
Product Code: LLZ
Federal Regulation: 21 CFR §892.2050
Manufacturing Facility: Bartron Medical Imaging, Inc.
91 Shelton Street
New Haven, CT 06511
Telephone: (203) 498-2184
Facsimile: (203) 498-2189

**Establishment
Registration Number:** N/A

Owner/operator number: N/A



Predicate Device

DEMASQ Imaging Software, manufactured by DEMASQ Ltd of Wales, United Kingdom and cleared under 510(k) #K090481 on March 19, 2009.

Intended Use / Indications for Use

MED-SEG is a software device that receives medical images and data from various imaging sources (including but not limited to CT, MR, US, RF units), computed and direct radiographic devices, and secondary capture devices, (scanners, imaging gateways or imaging sources). Images and data can be stored, communicated, processed and displayed within the system or across computer networks at distributed locations.

In addition to general PACS use, this system can be used by trained professionals (e.g. physicians, radiologists, nurses, medical technicians, and assistants) to separate 2D images into "digitally related" sections or regions that, after colorization, can be individually labeled by the user. These images can be used to find appropriate window/level settings, to facilitate report generation and communication, or for other uses. These processed images should not be used for primary image diagnosis.

Only DICOM "for presentation" uncompressed or non-lossy compressed images can be used on an FDA cleared or approved monitor for primary image diagnosis in mammography.

Technological Characteristics

MED-SEG™ software is a Picture Archiving and Communications System (PACS) for radiological image processing, storage, display and communication. The system can receive digital images via a secure internet communication link. The system incorporates parallel-computing algorithms that perform high-speed segmentation and regionalization. The system does not contact the patient nor does it control any life sustaining devices. A clinician interprets the images and information displayed by the system, providing ample opportunity for human intervention in the clinical decision process.

Performance Data

Laboratory testing documented that MED-SEG™ complies with the recognized consensus standards for radiological image processing systems.

Substantial Equivalence

MED-SEG™ is a PAC system that uses the same software technology, and complies with the same recognized consensus standards as its predicate device. It has the same intended use and indications for use as the predicate system and therefore is substantially equivalent.



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

Bartron Medical Imaging, Inc.
% Zvi Ladin, Ph.D.
Principal
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990 Washington Street, Suite 204
DEDHAM MA 02026

JUL 26 2010

Re: K092328
Trade/Device Name: MED-SEG™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 5, 2010
Received: February 16, 2010

Dear Dr. Ladin:

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.

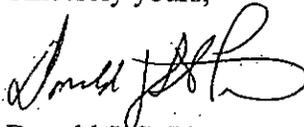
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

K092328

Indications for Use

JUL 26 2010

510(k) Number (if known): K092328

Device Name: MED-SEG™

Indications For Use: MED-SEG is a software device that receives medical images and data from various imaging sources (including but not limited to CT, MR, US, RF units), computed and direct radiographic devices, and secondary capture devices, (scanners, imaging gateways or imaging sources). Images and data can be stored, communicated, processed and displayed within the system or across computer networks at distributed locations.

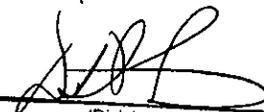
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Prescription Use AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ OIVD


(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K092328