



APR 29 2010

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

Mr. John Howlett  
Head of BSI Medical Device Notified Body  
BSI Group, Product Services  
British Standards Institution, Maylands Avenue  
Hemel Hempstead, Herts HP2 4SQ  
UNITED KINGDOM

Re: K100335  
Trade/Device Name: ORS Visual  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: LLZ  
Dated: March 22, 2010  
Received: March 25, 2010

Dear Mr. Howlett:

This letter corrects our substantially equivalent letter of April 8, 2010.

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.

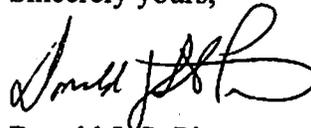
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

#### 4. INDICATIONS FOR USE

510(k) Number: Unknown

Device Name: ORS Visual

##### Indications for Use:

The ORS Visual is a software-based Picture Archiving and Communication System (PACS) used with general purpose computing hardware for the display and 3D visualization of medical image data. It provides for communication, storage, reformatting, rendering, and display of DICOM compliant image data derived from various sources including CT and MRI.

The ORS Visual software is intended for use as a diagnostic, review, and analysis tool by trained professionals such as physicians, technologists, and nurses. When interpreted by a trained physician, reviewed images may be used as an element for diagnosis. It is the user's responsibility to ensure that the software is installed on appropriate hardware and that image quality is suitable for the clinical application. Object Research Systems (ORS) recommends that users of the ORS Visual software consult the appropriate American College of Radiology Practice Guidelines pertaining to the anatomy and pathology being studied.

Mammographic and compressed images are not supported for viewing.

The software is not intended to replace the skill and judgment of a qualified medical practitioner and should only be used by people who have been appropriately trained in the software's functions, capabilities and limitations. Users should be aware that certain views make use of interpolated data. This is data that is created by the software based on the original data set. Interpolated data may give the appearance of healthy tissue in situations where pathology that is near or smaller than the scanning resolution may be present.

ORS Visual software must be installed on a suitable commercial computer platform. It is the user's responsibility to ensure the monitor quality and ambient light conditions are consistent with the clinical applications.

Typical users of ORS Visual are trained medical professionals, including but not limited to radiologists, clinicians, technologists, and others.

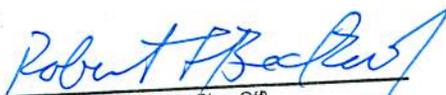
Prescription Use   X    
(Part 21 CFR 801 Subpart D)

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)~~ OTVD

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

510K

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