K111776

3.0 510(K) SUMMARY

Submission Date: **June 21, 2011**

Submitter Information:

Company Name: Riverain Medical Group, LLC.

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Device Information:

Trade Name: DeltaView™
Regulation Number: 21 CFR §892.2050
Regulation Name: System, Image Processing, Radiological
Regulatory Class: Class II
Product Code: LLZ

Predicate Device: SoftView
(K092363)
Riverain Medical Group, LLC
Class II

Device Description: DeltaView is a dedicated post-processing application which registers current and prior chest exams to provide an image that shows areas of change.

Intended Use: DeltaView is intended to generate a secondary residual image based on a current and prior chest x-ray image of the same patient.

Indications for Use: **DeltaView** is intended to generate a secondary residual image based on a current and prior chest x-ray image of the same patient, resulting in improved detection of lung nodules. The DeltaView image provides adjunctive information and is not a substitute for the original PA/AP image. This device is intended to be used by trained professionals, such as physicians and radiologists, on

patients with risk of having lung nodules, and is not intended to be used on pediatric patients.

Comparison to Predicate Device:

DeltaView is substantially equivalent to the cited predicate device. Differences in the design and performance from the cited predicate device do not affect either the safety or effectiveness of DeltaView for its intended use.

Conclusion:

DeltaView is a mathematical model of the current medical practice of manually comparing radiographic images. Radiologists routinely compare prior and current chest x-rays from the same patient, when available, to ascertain whether pathological change has occurred. The comparison requires the radiologist to associate regions of interest and neutralize the acquisition effects. DeltaView facilitates the comparison process through the automated formation of a difference image, by registering and subtracting a difference of normalized, bone suppressed image pairs. DeltaView achieves this using a variety of advanced image processing and pattern recognition methods. Just as the cited predicate device removes obstructions from a chest X-ray image in order to enhance the radiologist's detection of suspicious structures, so DeltaView obscures the unchanged portions of patient images taken over time in order to enhance the radiologist's detection of suspicious, changed structures. Furthermore, DeltaView uses the same bone suppression mechanism as the predicate device as part of its residual image algorithm. There are no new issues of safety and effectiveness raised by the incorporation of the predicate device's bone suppression in this new device.

Reader Study Results:

In a multi-reader multi-case (MRMC) reader study, radiologists interpreted pairs of images in order to compare the radiologists' ability to detect valid change when they were aided by the DeltaView image. Localized receiver operating characteristic curves (in terms of the trade-off between sensitivity and specificity when the decision criteria change) were used to evaluate radiologists' diagnostic performance in the detection of actionable lung nodules on chest radiographs with and without the usage of DeltaView. The results indicated that DeltaView should be

a useful adjunct for the interpretation of chest radiographs when looking for a change in a lung nodule.

The objective of the study was to demonstrate that a radiologist's results when using DeltaView images are superior to the radiologist's results when using standard prior and current AP/PA x-ray image pairs alone. Localized Receiver Operating Characteristic (LROC) Analysis and analyses for Sensitivity, Specificity, and Positive and Negative Predictive Value were performed. The research hypothesis indicating superiority was that the upper 95% confidence limit on the differences in the area under the DeltaView LROC curve (AUCDV) subtracted from the area under the Unaided LROC curve (AUCUA) is greater than or equal to 0.0.

There were significant changes when the DeltaView difference image was used. The area under the LROC curve (AUCLROC) increased from 0.477 to 0.536 (12.4%) ($p = 2.9E-05$)

Substantial Equivalence: The reader study described above used similar methods and achieved similar results to the reader study that was reviewed by FDA when clearing the predicate device (K092363). In both cases, an image processing application generates a secondary image for the radiologist to view, and in both cases, the use of this secondary image resulted in a statistically significant improvement in the radiologist's ability to detect actionable lung nodules.

It should also be noted that DeltaView automates the current clinical reading practice of manually comparing a current radiographic image with a prior image from the same patient.

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

Ms. Jennifer Vetter Butsch
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DEC 2 8 2011

Re: K111776
Trade/Device Name: DeltaView™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 12, 2011
Received: December 14, 2011

Dear Ms. Butsch:

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,

Mary S Pastel

Mary S. Pastel, Sc.D.
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): K111776

Device Name: DeltaView

Indications for Use:

DeltaView is intended to generate a secondary residual image based on a current and prior chest x-ray image of the same patient, resulting in improved detection of lung nodules that have changed between the two examinations. The DeltaView image provides adjunctive information and is not a substitute for the original PA/AP image. This device is intended to be used by trained professionals, such as physicians and radiologists, on patients with risk of having lung nodules, and is not intended to be used on pediatric patients.

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 K111776