510(k) Summary

A) Submitted by: INVIA, LCC
3025 Boardwalk, Suite 200
Ann Arbor, MI 48108
Registration Number: 3004993756
Operator Number: 9069896

AUG 0 4 2010

K101279

Contact: MEDIcept
200 Homer Ave
Ashland, MA 01721
F. David Rothkopf
508-231-8842
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B) Device Name: Corridor4DM v2010

Classification Name: System, Imaging Processing, Radiogical

Device Class: 21 CFR 892.1200 (KPS)
21 CFR 892.1750 (JAK
21 CFR 892.2050 (LLZ)

CLASS II

Product Code KPS, JAK, LLZ

C) Substantially Equivalent (predicate) device(s):

Device	Manufacturer	510(k) Number
Corridor4DM	INVIA, LLC	K080575
syngoCirculation DynamicPET	Siemens	K083327
Syngo® Circulation	Siemens	K063762
E.CAM	Siemens	K023190
Odyssey LX Model	Philips Medical	K003437

D) Device Description:

Corridor4DM v2010 is a comprehensive application designed to process, review, and quantitatively analyze nuclear medicine, PET, and CT patient studies. The application provides tools to process, quantify, and display static, dynamic, gated planar,- standard ungated ECT images, ECG gated ECT images, and dynamic ECT images. ECT data is displayed on both a slice-by-slice basis and as 3-dimensional surface- rendered images in

many user selectable formats. All of the image formats can be viewed as a single dataset or as a comparison of related datasets. Among several optional display screens are side-by-side displays optimized for the review of uncorrected and attenuation corrected cardiac images.

Corridor4DM v2010 algorithmically determines and displays the left ventricular endocardial and epicardial surfaces. These surfaces provide quantitative assessments of cardiac functions. Corridor-4DM v2010 includes the ability to save and export diagnostic findings in a variety of formats. The application generates DICOM multi-frame (MFSC) and secondary screen captures (SSC) in addition to producing static (JPEG, TIFF) and dynamic (AVI) image files.

Corridor4DM v2010 is intended to be used only by trained medical professionals. The Clinician retains the ultimate responsibility for making the pertinent assessment based on their standard practices and visual assessment.

F) Intended Use:

INVIA's Corridor4DM application is intended to provide processing, quantification, and multidimensional review of the biodistribution of radionuclides in the body using planar and tomographic images. The application performs quantitative measurements of tracer uptake over time to aid in the interpretation of myocardial perfusion emission tomographic images. Cardiac CT interpretation and calcium quantification are optional features that are integrated into Corridor4DM (SPECT-CT and PET-CT). The calcium scoring package is a non-invasive diagnostic tool that can be used to evaluate the calcified plaques in the coronary arteries, a risk factor for coronary artery disease. Co-registration or fusion of volumetric data (ECT and/or CT) is provided as a quality control for the identification of structures where correlative spatial information is necessary for a diagnostic interpretation.

G) Comparison to Predicate Device(s):

The Corridor4DM v2010 has the same technology, intended use, target population, and clinical setting as the predicate devices.

The chart below compares the Corridor4DM v2010 device to predicate devices.

Features	Corridor4DM v2010	Corridor4DM K080575	Syngo Circulation Dynamic K083327	Syngo Circulation K063762	E. CAM K023190	Odyssey K003437
Product Code	KPS, JAK, LLZ	KPS, JAK LLZ	LLZ	JAK	LLZ	LLZ
Reconstruction of tomographic datasets	Yes	No	No	No	Yes	Yes
Processing of Planar Images	Yes	No	No	No	Yes	Yes
Quantification of tracer uptake over time	Yes	No	Yes (PET only)	No	Yes (NM only)	Yes (NM only)
Digital image retrieval of radiographs	Yes	Yes	Yes	Yes	Yes	Yes
Quantitative Estimates of Cardiac Function	Yes	Yes	No	Yes	No	No
Quantitative estimates of cardiac perfusion	Yes	Yes	Yes	Yes	No	No

H) Safety and Effectiveness:

The Corridor4DM v2010 application and safety is assessed via the Risk Management Plan in accordance with ISO 14971.

I) Guidance Documents:

Guidance for the Submission of Premarket Notifications for Emission Computed Tomography Devices and Accessories (SPECT and PET) and Nuclear Tomography Systems; Final, FDA December 3, 1998

Guidance for the Submission of Premarket Notifications for Medical Image Management Devices Document issued on: July 27, 2000

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices; Final, FDA May 11, 2005

J) Conclusion:

Invia, LLC believes that the Corridor4DM v2010 is substantially equivalent to the predicate devices based on intended usage, technology comparison and system performance. Corridor4DM v2010 validation testing showed no new issues of safety and effectiveness when compared to predicate devices.

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

AUG 04 2010

INVIA, LLC
% Mr. F. David Rothkopf
President
MEDIcept, Inc.
200 Homer Ave
ASHLAND MA 01721

Re: K101279
Trade/Device Name: Corridor4DM v2010
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ, KPS, and JAK
Dated: April 26, 2010
Received: May 6, 2010

Dear Mr. Rothkopf:

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

Indications for Use

510(k) Number (if known): K101279

AUG 04 2010

Device Name: Corridor4DM v2010

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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 K101279