K122205

510(k) Summary

AUG 15 2012

Submitter Information

EXINI Diagnostics AB
Scheelevägen 19A
SE-223 70 Lund
Sweden

Contact Person: Allison Scott
317.569.9500
ascott@ansongroup.com

Date: June 6, 2012

Trade Name: EXINI

Common Name: Picture Archiving and Communications System (PACS)

Classification Name(s): System, Image Processing, Radiological

Classification Number: 21 CFR 892.2050, LLZ

Predicate Device(s)

510(k) Number	Device Name	Submitter Name
K111319	IBIS Explorer and Markup Software	MEDQIA

Device Description

The EXINI software provides trained health-care professionals and researchers with a software tool set for acceptance, transfer, storage, image display, manipulation and quantification of digital medical images. The software is intended to be used with images acquired using nuclear imaging (NM) and computed tomography (CT) modalities. The software provides general Picture Archiving and Communications System (PACS) tools and a clinical application for markup and analysis of bone lesions in bone scans. The software complies with the Digital Imaging and Communications in Medicine (DICOM 3) standard.
The software runs on a standard PC with Microsoft Windows operating system.

Intended Use(s)

EXINI is intended to be used by trained healthcare professionals and researchers for acceptance, transfer, storage, image display, manipulation, quantification and reporting of digital medical images. The system is intended to be used with images acquired using nuclear imaging (NM) and computed tomography (CT). The software provides general Picture Archiving and Communications System (PACS) tools and a clinical application for oncology including lesion marking and analysis.

Technological Characteristics

EXINI and the IBIS Explorer and Markup Software have similar technological characteristics in that they are both software devices that provide general PACS functions with DICOM compatibility and image display. Both devices use image processing techniques for segmentation of skeletal regions, normalization and hotspot contouring/segmentation. Both devices are semi-automatic in that they require a manual step (hotspot verification step) where the user reviews and edits the selection of hotspots that are used as input for quantitative analysis. Both devices perform quantitative analysis based on 2D ROI (regions of interests) measurements in whole-body bone scans.

Non-Clinical Performance Data

The verification and validation (V&V) plan including definition of test methods and acceptance criteria was designed to ensure equivalent performance with the predicate device. The verification included software unit testing, integration testing and software system testing with functional testing of all software requirements. The validation process was performed to ensure that the system meets the user needs specification. The V&V test results showed that EXINI meets its intended use, user needs and software requirements.

Clinical Performance Data

Clinical testing was not conducted to support this 510(k) submission.

Non-Clinical and Clinical Performance Data Conclusions

The non-clinical performance data concludes that the subject device has equal performance and raises no new questions of safety and effectiveness in comparison to the predicate device.

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

EXINI Diagnostics AB
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

AUG 15 2012

Re: K122205
Trade/Device Name: EXINI
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 24, 2012
Received: July 25, 2012

Dear Mr. Job:

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,

Janine M. Morris
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):

Device Name: EXINI

Indications for Use:

EXINI is intended to be used by trained healthcare professionals and researchers for acceptance, transfer, storage, image display, manipulation, quantification and reporting of digital medical images. The system is intended to be used with images acquired using nuclear imaging (NM) and computed tomography (CT). The software provides general Picture Archiving and Communications System (PACS) tools and a clinical application for oncology including lesion marking and analysis.

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 Diagnostics (OIVD)