K130277
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Section 5 -510(k) Summary

MAY 3 1 2013

Date Prepared: January 31, 2013

1.0 Manufacturing Establishment and Contact Information

1.1 Manufacturer Name and Address:

Hologic, Inc.
35 Crosby Drive
Bedford, MA 01730

1.2 Establishment Registration Number:

1221300

1.3 Name, Title, and Telephone Number of Contact:

Name: Eileen M. Boyle
Title: Regulatory Affairs Specialist III
Phone: (781) 999-7781
Fax : (866) 652-8674
Email : eileen.boyle@hologic.com

2.0 Device Identification

2.1 Device Trade Name:

Hologic® Single Energy (SE) Femur Exam

2.2 Common/Usual Name

Software for Bone Densitometers

2.3 Proposed Intended Use:

Single Energy (SE) Femur Exams are used to visualize focal reaction or thickening along the lateral cortex of the femoral shaft which may be accompanied by a transverse radiolucent line. Clinical correlation is advised as these features may be consistent with atypical femur fractures, a complication associated with long term use of antiresorptive therapy.

2.4 Comparison of the Indication for Use:

The proposed indication for use of the SE Femur scan is substantially equivalent to that of the predicate device. Like the proposed device, the predicate device is indicated for the visualization of bone deformities. The predicate device is indicated for the visualization of vertebral bone deformities (as well as for the visualization of abdominal aortic calcifications), whereas the proposed device is for the visualization of bone deformities of the femur.

Since the identical IVA-HD scan is used, the SE Femur scan and IVA scans offer the same fundamental device technology, image acquisition mode, acquisition speed, x-ray technique factors, vertical resolution, x-ray aperture, radiation dose, and image display supported by the bone densitometer. No changes were made to the image acquisition software, report structure, or performance specifications. No new safety and effectiveness questions were raised following the risk assessment for the proposed expansion of the IVA scan's intended use. Therefore, the expanded indication for use statement has no effect on the bone densitometer's safety or effectiveness.

3.0 Device Classification

3.1 Classification:
Class II

3.2 Classification Name and Rule
Bone Densitometer: 21 CFR 892-1170

3.3 Classification Panel
Radiology

3.4 Product Code
90 KGI

3.5 Prescription Use
The use of the Single Energy (SE) Femur Exam is restricted to prescription use only.

3.6 Predicate Devices

- 510(k) No: K060111
  Trade Name: IVA (MXA-II) software option for the X-Ray bone densitometer
  SE Date: 4/4/2006
  Manufacturer: Hologic, Inc.

4.0 Device Description

The proposed Hologic ® Single Energy (SE) Femur scan allows for the visualization of bone deformities of the femur, specifically focal reaction or thickening along the lateral cortex of the femoral shaft which may be accompanied by a transverse radiolucent line.

Hologic's Discovery (K023398) bone densitometer models: Discovery A, C, W, and SL consist of an examination table and a C-arm. At opposite ends of the C-arm an x-ray tube and a linear multi-detector array are mounted. The patient is positioned on the examination table between the x-ray tube and the detector array. The detector and x-ray source scan the patient axially using an x-ray fan beam perpendicular to the direction of movement. The x-ray source can be pulsed at a constant voltage to acquire exams as in the case of Hologic's Instant Vertebral Assessment (IVA) exams reviewed and cleared by FDA (K060111). Currently, two types of IVA scans are in use on the Discovery A, C, W, and SL bone densitometers; the IVA and the IVA-HD (High Definition). Both scans are used for the visualization of vertebral bone deformities. The IVA scan has a 10 second scan time, whereas the IVA-HD has a 15 second scan time. IVA-HD scans use a thinner aperture resulting in higher resolution and a lower total dose than IVA scans. The high resolution image of the single energy IVA-HD scan makes it ideal for use as a scan to visualize deformities in the femur.

5.0 Comparison of Technological Characteristics:

The Single Energy (SE) Femur Exam is substantially equivalent to that of the predicate device. Like the proposed device, the predicate device is indicated for the visualization of bone deformities. The comparison table summarizes the technological characteristics of the Single Energy Femur Exam and the IVA the predicate device:

Comparison table of the Single Energy Femur Exam and IVA:

Device Characteristics	Proposed 510(k) Device Single Energy Femur Exam	Hologic, Inc. IVA (K060111)
Method of Deformity Assessment	Visual)	Same
Fundamental Device Technology	DXA Bone Densitometer	Same
Exam Site	Femoral shaft	Lumbar and Thoracic Spine
Imaging Scan	IVA-HD	IVA-HD
Image Acquisition Mode	Single Energy Fan Beam Scan	Same
Acquisition Speed for 15.7" Scan	15 seconds	Same
X-ray Technique Factors	140 kVp @ 5 ma	Same
Vertical Resolution	1.4 lp/mm	Same
X-ray Aperture	0.25 mm (W) x 61 mm (L)	Same
Entry Dose	0.025 mGy	Same
Image Display	On screen display with image tools	Same
Device Output	Image of femoral shaft	Image of Lumbar and Thoracic Spine

6.0 Performance Testing

The SE Femur and IVA-HD scans offer the same fundamental device technology, image acquisition mode, acquisition speed, x-ray technique factors, vertical resolution, x-ray aperture, radiation dose, and image display supported by the bone densitometer. The Single Energy (SE) Femur Exam has the same technological characteristics as the predicate device. The identical IVA-HD scan is used for the acquisition of the lumbar and thoracic spine scan as is used for the proposed device for the acquisition of the SE Femur scan. The sole difference is in the positioning of the patient so that the targeted region (spine or femur) is imaged. No changes have been made to the software and both SE Femur and IVA scans can be viewed on the DXA system's screen and a report can be printed.

The information provided in the 510(k) submission is acceptable for the demonstration of substantial equivalence to the predicate device with respect to physical performance and testing

7.0 Substantial Equivalence

The Single Energy (SE) Femur Exam software is substantially equivalent to commercially IVA software option (K060111) which allows visualization of bone deformities. The predicate device provides substantially equivalent or the same intended use, features and functions as the proposed device.

8.0 Conclusion

The Hologic Single Energy (SE) Femur Exam software allows visualization of bone deformities. The features and functions are substantially equivalent to those of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 31, 2013

Hologic, Inc.
% Ms. Eileen M. Boyle
Senior Regulatory Affairs Specialist
35 Crosby Drive
BEDFORD MA 01730

Re: K130277
Trade/Device Name: Single Energy (SE) Femur Exam
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone densitometer
Regulatory Class: II
Product Code: KGI
Dated: May 15, 2013
Received: May 16, 2013

Dear Ms. Boyle:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/DeviceLabeling/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

SECTION 4 – INDICATIONS FOR USE

510(k) Number (if known): K130277

Device Name: **Single Energy (SE) Femur Exam**

Indications for Use:

Single Energy (SE) Femur Exams are used to visualize focal reaction or thickening along the lateral cortex of the femoral shaft which may be accompanied by a transverse radiolucent line. Clinical correlation is advised as these features may be consistent with atypical femur fractures, a complication associated with long term use of antiresorptive therapy.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of InVitro Diagnostic Device Evaluation and Safety

510(k) K130277