MAR 16 2011

F. 510(k) Summary

F.1 Manufacturing Establishment and Contact Information

F.1.1 Manufacturer Name and Address:

Hologic, Inc.
35 Crosby Drive
Bedford, MA 01730

F.1.2 Establishment Registration Number:

1221300

F.1.3 Name, Title, and Telephone Number of Contact:

Christina Hurton
Regulatory Affairs Specialist
Phone: (781) 999-7781
Fax: (866) 652-8674
Christina.Hurton@hologic.com

F.2 Device Identification

F.2.1 Device Trade Name:

Hologic Whole Body DXA Reference Database

F.2.2 Common / Usual Name:

Database for Bone Densitometers

F.2.3 Proposed Intended Use:

The Hologic Whole Body DXA Reference Database software used on Hologic QDR bone densitometers measures the regional and whole body bone mineral density, lean and fat tissue mass and calculates derivative values of bone mineral content, area, soft tissue mass, regional soft tissue mass, total soft tissue mass, fat free mass, regional and total soft tissue mass ratios, % fat, regional % fat, total body % fat, android % fat, gynoid % fat, android/gynoid ratio, and body mass index. The values can be displayed in user-defined statistical formats and trends with color image mapping, and compared to reference populations at the sole discretion of the health care professional.

These body composition values are useful to health care professionals in their management of diseases and conditions where the disease or conditions itself, or its treatment, can affect the relative amounts of fat and lean tissue. The Hologic Whole Body DXA Reference Database software does not diagnose disease, recommend treatment regimens, or quantify treatment effectiveness. Only the health care professional can make

these judgments. Some of the diseases and conditions for which body composition values are useful include chronic renal failure, anorexia nervosa, obesity, AIDS/HIV, and cystic fibrosis. DXA body composition is a useful alternative to hydrostatic weighting and skin fold measurements.

F.3 Device Classification

F.3.1 Classification:

Class II

F.3.2 Classification Name and Rule

Bone Densitometer: 21 CFR 892.1170

F.3.3 Classification Panel

Radiology

F.3.4 Product Code

90 KGI

F.3.5 Predicate Devices

- 510(k) No.: K071570
  Trade Name: Body Composition Software Option for GE Lunar DEXA Bone Densitometers
  SE Date: June 27, 2007
  Manufacturer: GE Medical Systems, Lunar

F.4 Conclusion:

The Hologic Whole Body DXA Reference Database does not change any of the algorithms or measured values of fat mass, lean mass or bone mass from the previously cleared APEX 2.0 Software (K072847). It does not change the fundamental scientific technology and no new safety or efficacy concerns are raised.

The Hologic Whole Body DXA Reference Database is substantially equivalent to the presently marketed predicate device: Body Composition Software Option for GE Lunar DEXA Bone Densitometers (K071570).

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. Christina Hurton
Regulatory Affairs Specialist
Hologic, Inc.
35 Crosby Drive
BEDFORD MA 01730

MAR 16 2011

Re: K103265
Trade/Device Name: Hologic Whole Body DXA Reference Database
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone Densitometer
Regulatory Class: II
Product Code: KGI
Dated: November 3, 2010
Received: November 26, 2010

Dear Ms. Hurton:

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

A.2 Indication for Use Statement

510(k) Number (if known): K103265

Device Name: Hologic Whole Body DXA Reference Database

Indication for Use:

The Hologic Whole Body DXA Reference Database software used on Hologic QDR bone densitometers measures the regional and whole body bone mineral density, lean and fat tissue mass and calculates derivative values of bone mineral content, area, soft tissue mass, regional soft tissue mass, total soft tissue mass, fat free mass, regional and total soft tissue mass ratios, % fat, regional % fat, total body % fat, android % fat, gynoid % fat, android/gynoid ratio, and body mass index. The values can be displayed in user-defined statistical formats and trends with color image mapping, and compared to reference populations at the sole discretion of the health care professional.

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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)

Mary S Pastel

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

510K K103265