K061561

JUL 28 2006

Section G
510(k) Summary

H. 510(k) Summary

H.1 Manufacturing Establishment and Contact Information

H.1.1 Manufacturer Name and Address:

Hologic, Inc.
35 Crosby Drive
Bedford, MA 01730

H.1.2 Establishment Registration Number:

1221300

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

Jeanette Schier-Pugsley
Regulatory Affairs Manager
Phone: (781) 999-7300, ex. 7406
Fax: (781) 999-0614
jschierpugsley@hologic.com

H.2 Device Identification

H.2.1 Device Trade Name:

Hip Structural Analysis (HSA) Software Option for the Hologic QDR X-Ray Bone Densitometers.

H.2.2 Common / Usual Name:

Software option for Bone Densitometers

H.2.3 Intended Use:

The Hip Structural Analysis (HSA) Option for QDR X-Ray Bone Densitometers uses data from conventional Dual Energy X-Ray Absorptiometry (DXA) scans to measure the distribution of bone mineral mass at specific cross sections of the hip and allows the physician to estimate structural properties of the hip, such as CSA, CSMI, Z and Buckling Ratio.

H.3 Device Classification

H.3.1 Classification:

Class II

H.3.2 Classification Name and Rule

Bone Densitometer: 21 CFR 892.1170

H.3.3 Classification Panel

Radiology

H.3.4 Product Code

90 KGI

H.3.5 Predicate Devices

- 510(k) No.: K023398
  Trade Name: Discovery Package for QDR Densitometers
  SE Date: November 8, 2002
  Manufacturer: Hologic, Inc.

- 510(k) No.: K011917
  Trade Name: Advanced Hip Assessment (AHA) Software for GE Prodigy x-ray bone densitometers.
  SE Date: August 3, 2001
  Manufacturer: GE Lunar Corporation

H.4 Conclusion:

Based on the scientific literature and testing supplied in the 510(k) submission, the Structural Analysis (HSA) Option for QDR X-Ray Bone Densitometers is substantially equivalent to the presently marketed Discovery Package for QDR Densitometers software (K023398) and the Advanced Hip Assessment (AHA) Software for GE Prodigy x-ray bone densitometers (K011917). No new safety and efficacy questions are raised with the HSA Software Option.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL 2 8 2006

Ms. Jeanette Schier-Pugsley, RAC
Regulatory Affairs Manager
HOLOGIC, Inc.
35 Crosby Drive
BEDFORD MA 01730

Re: K061561
Trade/Device Name: Hip Structure Analysis (HAS) Software Option for QDR X-Ray Bone Densitometers
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone densitometer
Regulatory Class: II
Product Code: KGI
Dated: June 2, 2006
Received: June 5, 2006

Dear Ms. Pugsley:

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 either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

A.2 Indications for Use Statement

510(k) Number (if known): 061561

Device Name: Hip Structural Analysis (HSA) Software Option for QDR X-Ray Bone Densitometers

The Hip Structural Analysis (HSA) Option for QDR X-Ray Bone Densitometers uses data from conventional Dual Energy X-Ray Absorptiometry (DXA) scans to measure the distribution of bone mineral mass at specific cross sections of the hip and allows the physician to estimate structural properties of the hip, such as CSA, CSMI, Z and Buckling Ratio.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use

(Per 21 CFR 801.109) (Optional Format 1)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061561