Section F.

510(k) Summary of Safety and Effectiveness:

Pediatric Reference Database

K041266

Submitter:	**Hologic, Inc.**
Submitter Address:	**35 Crosby Drive Bedford, MA 01730**
Contact Person:	**Richard L. Follett, V.P., Regulatory Affairs and Quality Assurance**
Phone Number:	**(781) 999-7506**
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Date Prepared:	**May 7, 2004**
Device Trade Name:	**Pediatric Reference Database**
Device Common Name:	**BoneDensitometer**
Device Classification Name:	**Bone Densitometer 21 CFR 892.1170**
Predicate Devices:	**Lunar Pediatric Reference Data (K001812) Expanded LUNAR Reference Data (K964307) NHANES Reference Data for QDR (K963363) Hologic® Discovery Package for QDR (K023398) Hologic® QDR Explorer X-Ray Bone Densitometer (K033224) QDR 4500 X-Ray Bone Densitometer (K943505)**

Device Description:

The Pediatric Reference Database is a software option which simply extends the existing, commercially available reference databases' ability to generate a Z-score for younger subjects.

The Pediatric Reference Database for the Hologic QDR Series X-Ray Bone Densitometers provides AP Spine, Hip and Whole Body densitometry reference data for male, female, white American children. The Pediatric Reference Data is used in conjunction with previously existing software in the QDR Series Densitometers which compares patient results to sex, ethnicity and age-matched values. The reference database is used to expand the range of bone densitometry reference values to include age 3-20 years of age. The software provides a comparison of Bone Mineral Density (BMD) measurements obtained by dual energy x-ray absorptiometry to a database of BMD reference values.

Patient results for each analysis region can be compared to reference values both graphically and quantitatively. Graphical plots of the age dependent reference Bone Mineral Density (BMD) values corresponding to the sex and ethnicity of the patient are generated with a marker placed at the position corresponding to the estimated patient BMD and age. Deviation "scores," are computed, quantifying (in population standard deviation units) the difference between the patient's estimated BMD and the mean value for age matched (Z-score) reference data. In addition, the patient BMD is expressed in percent of the age matched mean in percent of the pediatric mean.

Intended Use:

The Pediatric Reference Database is a software option used with Hologic QDR Series X-Ray Bone Densitometers. The software expands the range of bone densitometry reference data to include ages 3-20 years of age. The software provides a comparison of measured Bone Mineral Density (BMD) measurements obtained by dual energy x-ray absorptiometry to a database of BMD reference values in children. These data may be used for comparative purposes at the discretion of the physician.

Conclusion:

The Pediatric Reference Database is substantially equivalent to currently marketed software. No new safety and effectiveness questions are raised with the inclusion of these expanded reference values.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 11 2004

Ms. Anastasia C. Randall
Senior Regulatory Affairs Specialist
HOLOGIC, Inc.
35 Crosby Drive
BEDFORD MA 01730

Re: K041266
Trade/Device Name: Pediatric Reference Database
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone Densitometer
Regulatory Class: II
Product Code: 90 KGI
Dated: July 13, 2004
Received: July 14, 2004

Dear Ms. Randall:

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 (PMA), 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

Section D.

Indications for Use Statement

510(k) Number (if known): K041266

Device Name: Pediatric Reference Database

Indications for Use:

The Pediatric Reference Database is a software option used with Hologic QDR Series X-Ray Bone Densitometers. The Pediatric Reference Database is for use in determining Z-scores for subjects aged 3-20 years at the discretion of the physician.

(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)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041266