F. 510(k) Summary of Safety and Effectiveness

OCT 2 9 2004

F.1 Manufacturer Name and Address:

Hologic, Inc.
35 Crosby Drive
Bedford, MA 01730

F.2 Name, Title, and Telephone Number of Contacts:

Official Correspondent:
Richard L. Follett
Vice President, Regulatory Affairs and Quality Assurance
(781) 999-7506

Submission Correspondent:
Daniel F. Phelan
Senior Regulatory Affairs Specialist
(781) 999-7538

F.3 Date of Submission:

September 10, 2004

F.4 Device Identification

Trade Name: Infant Whole Body Software Option for QDR Densitometers
Common Name: Software Option for Bone Densitometer

F.5 Predicate Device Information

K023398 Discovery Package for QDR X-Ray Bone Densitometers
K961787 Body Composition Analysis Software for QDR X-Ray Bone Densitometers

F.6 Device Description and Intended Use

The Infant Whole Body software option for QDR X-Ray Bone Densitometers is an optional data acquisition and analysis method that provides estimates of bone mineral content (BMC, in grams), bone mineral density (BMD, in grams/cm^2), and body composition (lean body mass and fat mass of non-osseous tissues) in human infants from birth to one year of age. These data may be used at the discretion of a physician where medically necessary.

F.7 Substantial Equivalence

The Infant Whole Body Software Option is performs the same functions as the currently available Hologic Body Composition Software Option for QDR X-Ray Bone Densitometers (K961787) and the Discovery Package for Hologic QDR X-Ray Bone Densitometers (K023398).

The Infant Whole Body software option adds an optional scan type to the QDR XP Scan Module, and an optional analysis type to the QDR XP Analysis Module of the QDR for Windows software operating system.

The Infant Whole Body Software option performs the same functions as the currently commercialized Whole Body Software Option: the acquisition and analysis of whole body BMC (in grams), BMD (in grams per square centimeter), and body composition (%fat) for use

at the discretion of a physician. The only differences between the Infant Whole Body software option and the adult Whole Body Software Option are:

A modification to the Scan Module (data acquisition module) to enable a smaller region of interest (due to smaller subject size), thinner x-ray beam and slower scan speed to improve spatial resolution and bone edge detection, and

A modification to the Analysis Module (data analysis module) include an algorithm that employs lower bone and soft tissue detection thresholds suitable for detecting and evaluating low bone densities and low soft tissue masses found in human infants.

F.8 Tabular Comparison

Attribute	Hologic ® Body Composition Software Option for QDR® X-Ray Bone Densitometers	Hologic ®Discovery Package for QDR	Hologic® Infant Whole Body Software Option
510(k) Number	K961787	K023398	[redacted]
Indications for Use	Estimate the lean body mass and fat mass of non-osseous tissues in situations where medically necessary.	Estimation of bone mineral content (BMC), bone mineral density (BMD), comparison of measured variables to a database of reference values, the estimation of fracture risk, vertebral deformity assessment, body composition analysis, and discrimination of bone from prosthetics using Hologic QDR X-Ray Bone Densitometers.	The Infant Whole Body software option for QDR X-Ray Bone Densitometers is an optional data acquisition and analysis method that provides estimates of bone mineral content (BMC, in grams), bone mineral density (BMD, in grams/cm^2), and body composition (lean body mass and fat mass of non-osseous tissues) in human infants from birth to one year of age. These data may be used at the discretion of a physician where medically necessary.
Target Population	Children, Adolescents, Adult	Children, Adolescents, Adult	Infant
Age Range	3-80 years of age, depending on scan mode.	3-80 years of age, depending on scan mode.	Birth –1 year
Prescription Use	Required.	Same	Same
Acquisition Technique	Dual X-Ray Absorptiometry	Dual X-Ray Absorptiometry	Same
Analysis Regions	Spine, Femur, Whole Body	Lumbar Spine, Hip, Forearm, Whole Body, AP Lateral Spine	Spine, Femur, Whole Body
Operating Platform	Windows 98, Windows XP	Windows XP	Windows 98, Windows XP
Dual Energy X-Ray Production	Pulsed dual voltage x-ray tube	Same	Same
Scan Site	Whole Body	Whole Body, Hip, Spine, Forearm	Whole Body
Measurement Output (Results)	Global and Regional Bone and Body Composition Estimates	Same	Same
Report Screens	Bone Area, BMC, BMD, and Body Composition Reports	Same	Same

Attribute	Hologic ® Body Composition Software Option for QDR® X-Ray Bone Densitometers	Hologic ®Discovery Package for QDR	Hologic® Infant Whole Body Software Option
Calibration System (Bone Results)	Internal Reference system with bone equivalent material	Same	Same
Calibration System (Body Composition Results)	Aluminum and Acrylic Step Phantom	Same	Same
Scan Length	up to 77 inches	up to 77 inches	32 inches
Scanning Method	Multi-detector array, Indexing table, motorized C-arm	Same	Same
X-Ray System	Switched pulse dual-energy x-ray tube, operating at 100 and 140kV, 2.5mA average at 25% duty cycle, 5.0 mA average at 50% duty cycle (30s maximum), Tungsten target	Same	Same
Detection System	Multi-channel detector consisting of $CdWO_4$ scintillators coupled to Silicon diodes.	Same	Same
Scatter Dose Rate	Less than 10µGy/hr at 2m from the center of the X-Ray beam for BMC/BMD and Body Comp. scans	Same	Same
Leakage Radiation	Meets requirements of 21CFR 1020.30(k) for leakage from an x-ray source.	Same	Same
Calibration	Automatic Internal Reference System	Same	Same
Hologic Device Models	Discovery A/C/W, Delphi A/C/W, QDR 4500 A/C/W, Explorer	Discovery A/C/W/SL, Delphi A/C/W/SL, QDR 4500 A/C/W/SL, Explorer	Discovery A, Delphi A, QDR 4500 A

F.9 Conclusion

Hologic believes that the Infant Whole Body Software Option is substantially equivalent to currently marketed devices. No new issues of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 9 2004

Mr. Daniel F. Phelan
Senior Regulatory Affairs Specialist
HOLOGIC, Inc.
35 Crosby Drive
BEDFORD MA 01730

Re: K042480
Trade/Device Name: Infant Whole Body Software Option for Hologic QDR X-Ray Bone Densitometers
Regulation Number: 21 CFR §892.1170
Regulation Name: Bone densitometer
Regulatory Class: II
Product Code: 90 KGI
Dated: September 10, 2004
Received: September 13, 2004

Dear Mr. Phelan:

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.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (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

B.3 Indications for Use Statement

510(k) Number (if known): K042480

Device Name: Infant Whole Body Software Option for QDR X-Ray Bone Densitometers

Indications for Use:

The Infant Whole Body software option for QDR X-Ray Bone Densitometers is an optional data acquisition and analysis method that provides estimates of bone mineral content (BMC, in grams), bone mineral density (BMD, in grams/cm^2), and body composition (lean body mass and fat mass of non-osseous tissues) in human infants from birth to one year of age. These data may be used at the discretion of a physician where medically necessary.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use V 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 K042480