K961787

510(k) SUMMARY

JUN 13 1997

Hologic® Body Composition Software Option for QDR® X-Ray Bone Densitometers

Submitter Name:	Hologic, Incorporated
Submitter Address:	590 Lincoln Street Waltham, Massachusetts 02154
Contact Person:	Nandini Murthy, Regulatory Scientist
Phone Number:	(617) 890-2300
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Date Prepared:	May 8, 1996
Device Trade Name:	Hologic® Body Composition Software Option for QDR® X-Ray Bone Densitometers
Device Common Name:	X-Ray Bone Densitometer
Proposed Classification Name:	Body Composition Software Option for Bone Densitometer
Predicate Devices:	DPX Tissue Quantitation Output; Lunar Corporation CT 9800; General Electric Corporation
Device Description:	The Hologic® Body Composition Software Option for QDR® X-Ray Bone Densitometers is a software algorithm that permits an operator to display soft tissue characteristics. Soft tissue estimates are obtained using the Dual X-Ray Photon Absorptiometry (DXA) technique in which the x-ray tube emits alternating pulses of "high" and "low" energy x-rays which pass through the subject and are received by the detector array. The attenuation of the x-ray beam due to the subject is estimated by the detectors. By comparing the attenuation of the high and low energy pulses, the contributions of bone in the subject can be eliminated, leaving only the contributions due to non-osseous tissues.
Intended Use:	The intended use of the Hologic® Body Composition Software Option for QDR® X-Ray Bone Densitometers is to estimate the lean body mass and fat mass of non-osseous tissues in situations where medically necessary.

Device Technological Characteristics and Comparison to Predicate Devices:

There is no significant change from existing QDR® software for total body scans. However, as an optional feature, operators are now able to display soft-tissue characteristics, specifically estimation of lean body mass and fat mass of non-osseous tissues in situations where medically necessary.

Performance Data:

Published reports using *in vitro* and *in vivo* models have established the utility and validity of determining the soft tissue components of body composition with the QDR® devices. Studies included comparative experiments to evaluate DXA and other modalities commonly used for estimating body composition; normative data generated among healthy individuals spanning the adult age-range (as well as in children and adolescents); and the value of DXA among patients with syndromes known to affect body composition (e.g., AIDS and cystic fibrosis).

A study was also conducted to determine the strength of agreement among the QDR® models with the body composition software. Measurements were recorded for fat mass, lean mass, total soft tissue mass and percentage fat for each subject. All correlation coefficients were strongly positive; approximately 0.99 for each comparison. The incremental percentage difference among the models was small, ranging from approximately 0.5% for percentage fat to 2.5% for fat mass. These data support the conclusion that, in selected cases, such as monitoring of patients where marked changes in body composition are expected, the QDR® models may be used interchangeably, especially if attention is given to obtaining cross-calibration data.

Conclusion:

The Hologic® Body Composition Software Option for QDR® X-Ray Bone Densitometers is substantially equivalent to predicate devices for the intended use of estimation of lean body mass and fat mass of non-osseous tissues in situations where medically necessary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Nandini Murthy
Regulatory Scientist
Hologic, Inc.
590 Lincoln Street
Waltham, Massachusetts 02154

Re: K961787
Hologic Body Composition Software Option for
QDR® X-Ray Bone Densitometers
Dated: May 1, 1997
Received: May 5, 1997
Regulatory class: II
21 CFR 892.1170/Procode: 90 KGI

JUN 13 1997

Dear Ms. Murthy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591 for Radiology devices, or 594-4613 for Ear, Nose and Throat devices. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Hologic® Body Composition Software Option for QDR® X-Ray Bone Densitometers

Indications For Use:

The intended use of the Hologic® Body Composition Software for QDR® X-Ray Bone Densitometers is to estimate the lean body mass and fat mass of non-osseous tissues in situations where medically necessary.

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

Concurrence of CDRH; Office of Device Evaluation (ODE)

Prescription Use X OR... Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K961787