K 98 3028

510(K) SUMMARY

HOLOGIC® QDR® X-Ray Bone Densitometers with an added feature of Estimation of Fracture Risk from BMD*

Submitter Name:	Hologic, Incorporated
Submitter Address:	590 Lincoln Street Waltham, MA 02451
Contact Person:	Nandini Murthy, Regulatory Scientist
Phone Number:	(781) 890-2300
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Date Prepared:	August 28, 1998
Device Trade Name:	Hologic® QDR® X-Ray Bone Densitometers
Device Common Name:	X-Ray Bone Densitometer
Predicate Devices:	NORLAND-CAMERON Bone Mineral Analyzer, Model 178, Preamendment device. Norland model pDEXA Bone Densitometer with Fracture Risk Option. (K973104, FDA clearance Jan 29, 1998)
Device Description:	The Hologic QDR X-Ray Bone Densitometers with the added feature of estimation of Fracture Risk from BMD includes additional reports that provide an estimation of risk of fracture.
Intended Use:	The intended use of the Fracture Risk Option includes the World Health Organization's (WHO) definition of osteoporosis and osteopenia based on the T-score and provides an estimate of Fracture Risk assessment based on WHO classification. The physician uses the Fracture Risk report in conjunction with other risk factors to arrive at diagnostic and patient management decisions.

* BMD = Bone Mineral Density

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 1998

Nandini Murphy, RAC
Regulatory Scientist
Hologic, Inc.
590 Lincoln St.
Waltham, MA 02154

Re: K983028
Estimation of Fracture Risk from BMD using Hologic QDR x-ray Bone Densitometers
Dated: August 28, 1998
Received: August 31, 1998
Regulatory class: II
21 CFR 892.1170/Procode: 90 KGI

Dear Ms. Murphy:

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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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) 594-4613. 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/dsma/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

Indications for Use Statement

The intended use of the Hologic Fracture Risk Option includes an added feature of estimation of Fracture Risk from bone mineral density (BMD) using the Hologic QDR® X-Ray Bone Densitometers.

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K983028

Prescription Use ✓
(Per 21 CFR 801.109)

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