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510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

(Submitted in accordance with the requirements of 21 CFR 807.3)

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Date: June 4, 2003

Device/Trade Name: DXAVIEW™ Hip and Spine

Common/Usual Name: QCT Bone Densitometry

Classification Name: Bone Densitometer, 21 CFR 892.1170, Class II

Predicate Devices:

K992246: QCT Bone Mineral Analysis Software
Intended Use: QCT Bone Densitometry to estimate bone density and bone density changes, for monitoring therapy, and to estimate fracture risk.

K941127: OCT Bone Mineral Analysis Software
Intended Use: Estimation of bone density in the spine.

K943505: Hologic QDR 3000 X-Ray Bone Densitometer
Intended Use: Estimate bone mineral density and bone mineral content at various anatomical sites.

K002113: CTXA Hip
Intended Use: Estimate bone density and bone mineral content in the hip. Compare to reference data to determine T-Scores and fracture risk.

Device Description:

The DXAView™ Hip and Spine are software Options to the Image Analysis QCT-3D Plus product, which provides 3D projection measurements similar to conventional DXA. The product Options provide estimates of bone mineral content (BMC) and bone density (BMD) of the proximal femur and spine. BMC is expressed in grams and BMD in g/cm^2 of calcium hydroxyapatite. DXAView™ uses phantom calibration by Quantitative Computed Tomography (QCT) on all compatible CT scanners. The computations are performed on 3D CT volumetric image sets obtained with conventional CT protocols and radiation doses.

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Intended Use:

The DXAView™ Hip and Spine bone densitometry options are intended to estimate bone mineral content (BMC) and bone mineral density (BMD) in the proximal femur and spine. The BMD may be compared to DXA reference data. T-Scores and Z-Scores are calculated with respect to young normal and age matched reference data, and can be used by the physician in determining fracture risk.

Summary of Fundamental Scientific Technology and Comparison with Predicate Devices:

The DXAVIEW™ bone densitometry Options provide estimates of bone mineral content (BMC) and bone mineral density (BMD) values similar to those obtained from the predicate DXA device (K943505: Hologic QDR 3000 X-Ray Bone Densitometer) for regions of interest in the proximal femur and spine. The predicate device, CTXA Hip K002113 measures bone density in the hip using calibrated CT volumetric images, and is highly similar to DXAVIEW™. DXAVIEW™ uses the same scanning and calibration procedures to acquire and calibrate the CT image as are used for the predicate device K992246: QCT Bone Mineral Analysis Software. NHANES III Standardized Reference Data are used to calculate T-Scores and Z-Scores. Pearson's R values between DXA and DXAVIEW™ on clinical comparison studies has been shown to be 0.93 to 0.94 for the neck and total femur regions. The uncertainty between the two results are about 1/3 of 1 population Standard Deviation (T=1/3), and are quite acceptable. The DXAVIEW™ BMD estimates are compared to reference populations to determine T-Scores, which assists physicians in identifying patients with low bone density and estimating fracture risk.

Summary of Clinical Performance Data:

Patient validation studies indicate a software precision of 0.012 g/cm² for total femur and 0.017 g/cm² for the femoral neck. Clinical studies comparing DXA and DXAVIEW™ for BMD of the hip showed correlation coefficients R of 0.93-0.94 for the total femur and femoral neck.

Conclusions:

The DXAVIEW™ Hip and Spine Bone Densitometry Options are substantially equivalent to the predicate devices while producing comparable results. Correlations between DXAVIEW™ and DXA are on the order of 0.93 and sufficiently high to warrant the use of the NHANES III Reference Data. The radiation dose resulting from the CT Scans used for analysis by the DXAVIEW™ software is comparable to other CT studies.



Signature

Ben Arnold, Ph.D.

Printed Name

President

Title



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 2003

Ben Arnold, Ph.D.
President
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Re: K031991
Trade/Device Name: DXAVIEW™
Regulation Number: 21 CFR 892.1170
Regulation Name: Radiographic Bone Densitomer
Regulatory Class: II
Product Code: 90 KGI
Dated: June 19, 2003
Received: July 30, 2003

Dear Dr. Arnold:

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 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.

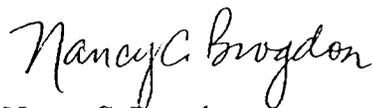
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

