

RA 71735

DEC - 2 1997

510(k) Summary

Schick accuDEXA Bone Densitometer

Common/Classification Name: Bone Densitometer
21 CFR 892.1170

Schick Technologies, Inc.
31-00 47th Avenue
Long Island City, NY 11101
718-937-5765, 718-937-5962 (FAX)
Contact: Enrico Renzi, Prepared: May 8, 1997

A. LEGALLY MARKETED PREDICATE DEVICES

The **accuDEXA** is substantially equivalent to bone densitometers currently marketed in the U.S. The Osteogram Radiographic Absorptiometry (RA) device, a pre-Amendment device originally from Compumed (now distributed by Merck), is similar in that it uses the three middle fingers of the hand to compute the bone density, though it uses X-ray film for recording. The Hologic QDR 2000+ DXA bone densitometer (K913321) is similar in that it uses the same dual-energy x-ray absorptiometry (DXA) technology, though it uses the forearm as the measurement site. The Schick CDR Digital Dental X-ray Receptor Array (K933455) currently marketed by Schick Technologies uses a similar digital imaging array.

B. DEVICE DESCRIPTION

The **accuDEXA** device is a Dual Energy X-Ray Absorptiometer (DEXA) device. The device is intended to calculate an index of bone mineral density in the middle finger of the non-dominant hand. By changing the high voltage on the X-ray tube, two energies are produced. Each of the two settings produces an image of the finger and each image is analyzed using various algorithms to produce a value of bone mineral density (BMD) and bone mineral content (BMC). These values are compared with a normative database, yielding a t-score and a z-score. The t-score is the number of standard deviations that the patient is above or below the mean of a reference sample of young healthy individuals. The z-score is the number of standard deviations that the patient is above or below the mean of a reference sample of individuals of the same age as the patient.

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C. INDICATIONS FOR USE

The accuDEXA is a dual-energy x-ray device indicated for use in measuring an index of the bone density of the middle finger of the non-dominant hand (BMD). This BMD value is a relative indicator of bone density elsewhere in the body. The measurement is compared to similar measurements from patients of the same gender and ethnicity to provide t-scores (number of standard deviations above or below the mean for a reference group of young healthy individuals) and z-scores (number of standard deviations above or below the mean for a cohort of the same age). A t-score or a z-score may be used by a physician as one factor, in conjunction with other clinical indicators, to diagnose osteoporosis and other bone disorders. When a normative database of the same ethnicity and gender is not available, the BMD value may still be used to compare to the patient's own baseline value, for example in following the patient's response to treatment for osteoporosis.

Below normal bone density can be associated with a variety of conditions or disorders of bone. For example, the Society of Nuclear Medicine and American College of Nuclear Physicians has identified specific medical indications for measurement of a patient's bone mass: for patients with premenopausal oophorectomy, spontaneous menopause, or estrogen deficiency conditions; for treatment-related osteopenia; when the diagnosis of osteopenia is suggested or established by other means, such as x-ray; during long-term immobilization; for endocrinopathies known to be associated with osteopenia; for post-gastrectomy and other malabsorption states leading to osteopenia; during long-term corticosteroid therapy; for chronic renal disease, particularly in childhood or adolescence; and to monitor treatment programs for osteoporosis.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The intended use for the accuDEXA and the predicate devices is the same. The **accuDEXA Bone Densitometer** has the same technological characteristics as the predicate devices. However, the descriptive characteristics may not be sufficiently precise to assure substantial equivalence. Therefore, Schick Technologies sponsored performance tests on the device and the predicate devices (see Section F, below), and a comparison of these data demonstrate that the **accuDEXA Bone Densitometer** is substantially equivalent to the predicate devices.

E. TECHNOLOGICAL CHARACTERISTICS

See Device Description, above.

F. TESTING

Schick Technologies has sponsored a study on cadavers that examines the precision and accuracy of the accuDEXA device. The study also directly compared the bone density values obtained with the predicate devices. This study showed that the accuDEXA measurements are very repeatable, even with repositioning. The very high correlation of the accuDEXA measurements with the ashed bone weights shows that the accuDEXA measurements are very accurate. The good correlation of the accuDEXA measurement with measurements with the two predicate devices demonstrates that the accuDEXA results for the middle finger are at least as good an indicator of BMD as the currently marketed predicate devices.

A reference data base has been developed in a clinical study which allows the calculation of t-scores and z-scores for each patient.

G. CONCLUSIONS

Schick Technologies has demonstrated through its comparison of characteristics with the predicate devices and comparison of performance testing with the predicate devices that the accuDEXA Bone Densitometer is substantially equivalent to the predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Schick Technologies, Inc.
c/o T. Whit Athey, Ph.D.
Senior Consultant
C.L. McIntosh
& Associates, Inc.
12300 Twinbrook Parkway, Suite 625
Rockville, Maryland 20852

Re: K971735
AccuDEXA Bone Densitometer
Dated: September 11, 1997
Received: September 11, 1997
Regulatory class: II
21 CFR 892.1170/Procode: 90 KGI

Dear Dr. Athey:

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 requirement, 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/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

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Sincerely yours,

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

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K971735

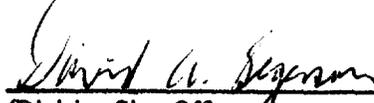
Device Name: Schick accuDEXA Bone Densitometer

Indications For Use:

The accuDEXA is a dual-energy x-ray device indicated for use in estimating the bone density of the middle finger of the non-dominant hand (BMD). This BMD value is a relative indicator of bone density elsewhere in the body.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971735

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____