

K981124

510(k) Summary

Schick accuDEXA Bone Densitometer Fracture Risk Claim

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: March 6, 1998

A. LEGALLY MARKETED PREDICATE DEVICES

The **accuDEXA Bone Densitometer** is substantially equivalent to the Norland pDEXA and Model 178 bone densitometer devices with respect to the fracture risk claim. The Norland pDEXA device was found to be substantially equivalent (K973104) with regard to claims of fracture risk to the Norland Model 178, which has been determined by CDRH to have been in commercial distribution prior to May 28, 1976 for use as an aid to the physician in determining fracture risk. The Norland pDEXA device was originally cleared under K931996.

B. DEVICE DESCRIPTION

The accuDEXA device is a Dual Energy X-Ray Absorptiometer (DEXA) device. The device is intended to estimate 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.

000018

77

C. 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. accuDEXA BMD estimates can be used as an aid to the physician in determining fracture risk.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The addition to the indications statement for the accuDEXA and the *indications statement cleared by FDA for the predicate device* are the same. The **accuDEXA Bone Densitometer** has the same technological characteristics as the predicate devices. The descriptive characteristics with respect to the fracture risk claim are precise enough to assure substantial equivalence. Therefore, the **accuDEXA Bone Densitometer** is substantially equivalent to the predicate devices with respect to the fracture claim.

E. TECHNOLOGICAL CHARACTERISTICS

See Device Description, above.

F. FRACTURE RISK DETERMINATION

The recommendations of the World Health Organization and the National Osteoporosis Foundation were used in developing a modification to the patient report printout, an addition to the User Manual, and a Patient Information Brochure.

G. CONCLUSIONS

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

000019

SD



JUN 4 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Schick Technologies, Inc.
Whit Athey
c/o C.L. McIntosh & Associates, Inc.
12300 Twinbrook Parkway, Suite 625
Rockville, MD 20852Re: K981124
accuDEXA Bone Densitometer
Dated: March 25, 1998
Received: March 27, 1998
Regulatory class: II
21 CFR 892.1170/Procode: 90 KGI

Dear Mr. 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 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

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): _____

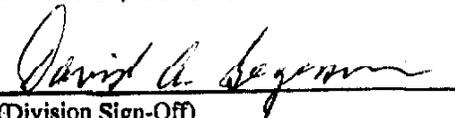
Device Name: Schick accuDEXA Bone Densitometer

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. accuDEXA BMD estimates can be used as an aid to the physician in determining fracture risk.

(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 K981124

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

000023