MAY 2 6 2000

K001429
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Exhibit IV: 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: February 15, 2000

A. Legally Marketed Predicate Devices

The original accuDEXA premarket notification was cleared on December 2, 1997 (K971735). Subsequently, a fracture risk claim was cleared on June 4th, 1998 (K981124). The proposed device modification alters and further clarifies some issues regarding the collection of the normative database. The device is otherwise unchanged and is substantially equivalent to the already cleared machine.

B. Modification Description

The purpose of this device modification is to add 80-89 year-old information to the Asian database with fewer normative data points and to include Latin American Hispanic data within the existing Hispanic database.

C. Indications for Use

This device modification in no way alters the indications for use of this machine beyond what was originally approved in K971735 and K981124. The original 510(k) stated that "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." The subsequent 510(k) further stated that "accuDEXA BMD estimates can be used as an aid to the physician in determining fracture risk".

D. Substantial Equivalence Summary

Functionality, indications for use, and technical characteristics of the **accuDEXA** are unchanged. The submission amends some of the specific details regarding the criteria that define the collection of the normative database. Schick Technologies has performed a risk analysis and validation study to demonstrate

that the accuDEXA Bone Densitometer is substantially equivalent to the already cleared machine.

E. Technological Characteristics

The technological characteristics of this machine are unchanged from those in the original 510(k) documents. The proposed changes are implemented through a simple software modification.

F. Risk Analysis and Validation study

Schick Technologies determined the risk associated with making the intended changes to be negligible. The changes result from a study that varied from the protocol described in the original 510(k). Statistical tests demonstrated similarity between the existing databases using already cleared criteria and modified Asian and Hispanic databases using criteria proposed in this document. Statistical equivalence was determined with a 95% confidence level. The inclusion of these databases does not introduce any additional risk to the accuDEXA device.

G. Conclusions

Schick Technologies has demonstrated through a risk analysis and validation studies that the device modification is substantially equivalent to the already cleared and marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 6 2000

Mr. Daniel Michaeli, M.S.
Product Manager
Schick Technologies, Inc.
31-00 47th Avenue
Long Island, NY 11101

Re: K001429
Schick accuDEXA® Bone Densitometer
(software modification)
Dated: May 1, 2000
Received: May 5, 2000
Regulatory Class: II
21 CFR §892.1170/Procode: 90 KGI

Dear Mr. Michaeli:

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 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). 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) 594-4591. 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 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K00 1429

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)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

David A. Bergman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K001429