DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

OCT 19 1989

Image Enhancements
Attn: Audie Chason
564 Mission Street
Suite 236
San Francisco, California 94105

Re: K894854/A
QCT Bone Mineral Density Analysis Software
Dated: September 19, 1989
Received: Undated
Regulatory class: II

Dear Mr. Chason:

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 to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (act). The general controls provisions of the act include requirements for annual registration, listing of devices, good manufacturing practices, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Performance Standards) 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. In addition, the Food and Drug Administration (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 the Radiation Control for Health and Safety Act of 1968, or other Federal laws or regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a pre-Amendments device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device, please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-8040. Other general information on your responsibilities under the act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

George C Murray

George C. Murray, Ph.D.
Director
Division of Anesthesiology, Neurology, and Radiology Devices
Office of Device Evaluation
Center for Devices and Radiological Health

QCT Software System
501(k) Submission
Audie Chason, Image Enhancements

1. Introduction:

The method of Quantitative Computed Tomography (QCT) has been established as a means of non-invasive quantitative bone mineral determination[1].

The QCT software system, developed by Image Enhancements Inc., allows the user to enter into a computer information obtained from executing a single energy measurement protocol with a commercially avaliable CT scanner. From the information entered by the user, the system provides an estimate of bone mineral content.

The QCT software system is substantially equivalent to predicate device [name of predicate device and 510(k) information]. In this paragraph the manufacturer (we) must carefully establish and formally document a basis for determining this equivalence.

2. Level of Concern:

The QCT software system does not interface directly with a medical device. Its function is to provide a means of entering, storing and obtaining information/data only. A competent health professional is reasonably expected to exercise judgement in the use of the information provided by the system. The system is substantially equivalent to predicate device [name of predicate device]. For these reasons, the QCT software system is determined to have a minor level of concern.

3. Functional Requirements:

The functional requirements of the QCT software system are as follows:

3.1
The QCT software system shall [1] provide a means of entering general patient information into a computer and electronically storing this information. The information may include:

1. General patient information, including patient sex and age.

2. Information on the CT scanning parameters used in performing the single energy measurement protocol.

3. The Hounsfield numbers from regions of interest (ROI) of CT data.

3.2
The QCT software system shall [1] provide an estimate of bone mineral density (BMD) content for each region of interest (ROI) for which Hounsfield numbers were entered.

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[1] Diagnosis and Assessment of Osteoporosis Using Quantitative CT, Applied Radiology, August 1987, p 55-61. See Exhibit A.