QUS-2 Calcaneal Ultrasonometer - P990039

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name:	QUS-2 Calcaneal Ultrasonometer
Manufacturer:	Metra Biosystems
Address:	265 N. Whisman Road, Mountain View, CA 94043
Approval Date:	August 8, 2000
Approval Letter:	http://www.fda.gov/cdrh/pdf/p990039a.pdf

What is it? The QUS-2 Calcaneal Ultrasonometer is a portable medical device that uses ultrasound to measure the strength of the heel bone (calcaneus). Since the heel bone is similar to the bones in the hip and spine, this measurement can indicate the strength of those bones as well.

How does it work? The QUS-2 sends a beam of ultrasound across the heel to a detector that measures the strength of the beam after it has passed through the bone. This is then compared to the average of measurements that have been obtained from young, healthy Caucasian (white) women. If the two measurements are similar, the patient's bone strength is considered normal. If the patient's measurement shows a lower strength than the normal value, this may indicate that the patient has osteoporosis, a thinning and weakening of the bone that can increase the risk of fracture. Although osteoporosis most often occurs in women past menopause, thinning and weakening of the bone can also occur in younger people with certain diseases. For these people, the measurement from the QUS-2 can be compared to normal values that take into account age, gender and ethnic background.

When is it used? To measure the bone loss of women past menopause, as well as other patients who may have diseases that cause bone loss.

What will it accomplish? The physician can use the results of the QUS-2 heel bone test, along with other clinical risk factors, to diagnose osteoporosis, to estimate the risk of fracture, and to detect other medical conditions that can result in bone loss.

When should it not be used?

- On patients under 20 or over 80 years old, as the meaning of measurements on such patients has not been determined
- On feet with open skin or sores

What are the limitations of this and ALL machines that measure bone density?

- A single reading may suggest an increased fracture risk, but cannot predict whether or not a fracture will occur.

- Measurements should only be compared to other measurements from machines of the same make and model.

Additional information: The SSED and Labeling will be available at:
http://www.fda.gov/cdrh/pdf/p990039.html
Other: http://www.fda.gov/womens

(Updated 6/12/2001)