As of **January 4, 2007** the contact information for this document has been updated to the following:

For questions regarding the use or interpretation of this guidance contact Robert A. Phillips at 240-276-3666 or by electronic mail at RobertA.Phillips@fda.hhs.gov

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 25 1997

Notice to manufacturers of bone mineral densitometers

Re: The claim of "fracture risk determination" for bone densitometers

On September 4, 1997, the Center for Devices and Radiological Health (CDRH) determined that the Norland Model 178 bone densitometer was in commercial distribution, for use as an aid to the physician in determining fracture risk, prior to May 28, 1976, the enactment date of the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act. This means that manufacturers wishing to market a bone densitometer with a similar claim can do so using the Norland Model 178 as a predicate for the claim.

Manufacturers wishing to make this claim should submit a new 510(k). As with all 510(k) submissions, you should establish that the new or modified device is substantially equivalent to the predicate(s). In addition to the normal labeling, please provide patient labeling that describes osteoporosis, explains why the disease is of concern to women, explains the measurement of bone density using your device, and explains how the results are used *(i.e., How does it work? What will it tell me? Why is this important? What other tests are available?)* The publications of several professional organizations may partially satisfy this request.

If you have any questions concerning this decision, please contact Robert Phillips, Ph.D., at (301) 594-1212.

Sincerely yours,

Lillian Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive, Abdominal,
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