

FEB 24 1986

TO: All Diagnostic Ultrasound Manufacturers and Importers

SUBJECT: Exemption from Reporting under 21 CFR 1002

Background

All electronic products that emit radiation, including ultrasound, are subject to the requirements of the Radiation Control for Health and Safety Act of 1968 (RCHSA). Section 1002 of Title 21 of the Code of Federal Regulations (21 CFR 1002) requires that manufacturers and importers of ultrasonic equipment file initial and model change reports on the radiation safety and testing of their products prior to introduction into commerce. In addition, diagnostic ultrasound products are subject to the requirements of Section 510(k) of the Food, Drug and Cosmetic Act. Since information required to be submitted under the RCHSA is very similar to that required to be submitted in 510(k) notifications, some manufacturers have requested relief from this duplication.

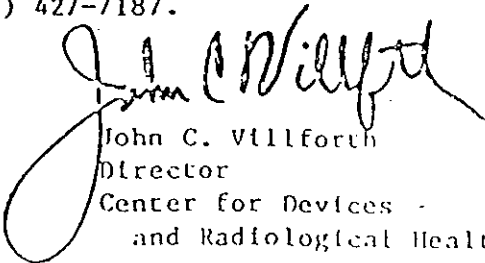
Policy

Under the authority of 21 CFR 1002.50(b), all manufacturers and importers of diagnostic ultrasound products are hereby exempted from initial and model change report requirements under 21 CFR 1002.10 and 1002.12. This exemption will not apply if the firm fails to comply with the requirements for 510(k) notifications. The Center for Devices and Radiological Health reserves the right to withdraw this exemption from any firm if it finds, through inspections under the Good Manufacturing Practice (GMP) requirements of 21 CFR 820 or through other means, that any of their products fail to conform to the product description in the 510(k) notice.

Manufacturers are not exempt from the requirements of 21 CFR 1002.20 (Reporting of Accidental Radiation Occurrences) nor the requirements of 21 CFR 1003 (Notification of Defects or Failure to Comply) and 1004 (Repurchase, Repair, or Replacement of Electronic Products).

Invitation to Comment

All questions or comments may be directed to Ms. Joanne Barron, Chief, Microwave/Acoustics Products Section, FDA (HFZ-312), 8757 Georgia Avenue, Silver Spring, MD 20910; telephone (301) 427-7187.



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