products on the Commerce Control List is controlled according to the provisions in each Category.

''Technology'' ''required'' for the ''development,'' ''production,'' or ''use'' of a controlled product remains controlled even when applicable to a product controlled at a lower level.

General License GTDR, without written assurance, is available for ''technology'' that is the minimum necessary for the installation, operation, maintenance (checking), and repair of those products that are eligible for General Licenses or that are exported under a validated export license.

**N.B.:** This does not allow release under a general license of the repair ''technology'' controlled by 1E02.e, 1E02.f, 7E03, or 8E02.a.

**N.B.:** The 'minimum necessary' excludes ''development'' or ''production'' technology and permits ''use'' technology only to the extent ''required'' to ensure safe and efficient use of the product. Individual ECCNs may further restrict export of 'minimum necessary' information.

General License GTDA is available for ''technology'' that is publicly available or technology arising during or resulting from fundamental research. See section 779.3 of this subchapter for details on General License GTDA.)

2. *General Software Note.* General License GTDR, without written assurance, is available for release of software that is generally available to the public by being:

a. Sold from stock at retail selling points, without restriction,[1] by means of:

1. Over the counter transactions;

2. Mail order transactions; or

3. Telephone call transactions; and

b. Designed for installation by the user without further substantial support by the supplier.

General License GTDA is available for software that is publicly available.

**N.B.;** The General Software Note does not apply to exports of ''software'' controlled by other agencies of the U.S. Government (see § 770.10 of this subchapter).

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 892

**[Docket No. 94N–0345]**

## Medical Devices; Classification of Transilluminators (Diaphanoscopes or Lightscanners) for Breast Evaluation

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing a final rule to classify the transilluminator (diaphanoscope or lightscanner) for breast evaluation into class III (premarket approval). This action is necessary to require manufacturers of transilluminators to submit a premarket approval application that includes information concerning safety and effectiveness tests for the device. This action is being taken under the Federal Food, Drug, and Cosmetic Act as amended by the Medical Device Amendments of 1976 and the Safe Medical Devices Act of 1990.

**EFFECTIVE DATE:** August 17, 1995.

**FOR FURTHER INFORMATION CONTACT:** Robert A. Phillips, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1212.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of January 13, 1995 (60 FR 3168), FDA issued a proposed rule to classify transilluminators (diaphanoscopes or lightscanners) for breast evaluation into class III. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application that includes information concerning safety and effectiveness tests for the device. A period of 90 days was provided for interested persons to submit written comments to FDA. FDA did not receive any comments on the proposal. Accordingly, the proposed rule is being adopted without change.

### Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

### Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the agency believes only a small number of firms will be affected by this rule, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

### List of Subjects in 21 CFR Part 892

Medical devices, Radiation protection, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 892 is amended as follows:

## PART 892—RADIOLOGY DEVICES

1. The authority citation for 21 CFR part 892 continues to read as follows:

**Authority:** Secs. 501, 510, 513, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. New § 892.1990 is added to subpart B to read as follows:

### § 892.1990 Transilluminator for breast evaluation.

(a) *Identification.* A transilluminator, also known as a diaphanoscope or lightscanner, is an electrically powered device that uses low intensity emissions of visible light and near-infrared radiation (approximately 700–1050 nanometers (nm)), transmitted through the breast, to visualize translucent tissue for the diagnosis of cancer, other conditions, diseases, or abnormalities.

(b) *Classification.* Class III (premarket approval).

(c) *Date premarket approval (PMA) or notice of completion of a product development protocol (PDP) is required.* The effective date of the requirement for premarket approval has not been established. See § 892.3.

Dated: July 10, 1995.

**Joseph A. Levitt,**

*Deputy Director for Regulations Policy, Center for Devices and Radiological Health.*

[FR Doc. 95–17640 Filed 7–17–95; 8:45 am]

**BILLING CODE 4160–01–F**

[1] The phrase ''without restriction'' clarifies that software is not ''generally available to the public'' if it is to be sold only with bundled hardware generally available to the public. Software that is both bundled with hardware and ''generally available to the public'' does qualify for General License GDTR, without written assurance.