(c) *Application procedure.* Applications for blanket certificates must be accompanied by the fee prescribed in § 381.207 of this chapter or a petition for waiver pursuant to § 381.106 of this chapter, and shall state:

* * * * *

(d) *Effect of certificate.* (1) Any certificate granted under this section will authorize the certificate holder to engage in transactions of the type authorized by subparts C and D of this part.

* * * * *

(e) *General conditions.* (1) Except as provided in paragraph (e)(2) of this section, any transaction authorized under a blanket certificate is subject to the same rates and charges, terms and conditions, and reporting requirements that apply to a transaction authorized for an intrastate pipeline under subparts C and D of this part.

* * * * *

(g) *Hinshaw pipeline without blanket certificate.* A Hinshaw pipeline that does not obtain a blanket certificate under this section is not authorized to sell or transport natural gas as an intrastate pipeline under subparts C and D of this part.

* * * * *

114. Sections 284.225 and 284.226 are removed and reserved.

115. In § 284.227, paragraph (d) is removed, and paragraphs (e), (f), and (g) are redesignated (d), (e), and (f).

### Subpart J—Blanket Certificates Authorizing Certain Natural Gas Sales by Interstate Pipelines

#### § 284.288 [Removed]

116. Section 284.288 is removed and reserved.

### Subpart L—Certain Sales for Resale by Non-interstate Pipelines

117. In § 284.402, paragraph (c)(1) is revised to read as follows and in the first sentence of paragraph (c)(2) the word ''criteria'' in paragraph (c)(2) is removed, and the word ''criterion'' is added in its place:

#### § 284.402 Blanket marketing certificates.

* * * * *

(c)(1) The authorization granted in paragraph (a) of this section will become effective for an affiliated marketer with respect to transactions involving affiliated pipelines when an affiliated pipeline receives its blanket certificate pursuant to § 284.284.

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[FR Doc. 95–653 Filed 1–12–95; 8:45 am]

BILLING CODE 6717–01–P

## 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:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to classify the transilluminator (diaphanoscope or lightscanner) for breast evaluation into class III (premarket approval). The agency is also publishing in this document the recommendations of the Obstetrics and Gynecology Devices Panel regarding the classification of the device. After considering public comments on the proposed classification, FDA will publish a final regulation classifying the device. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) and the Safe Medical Devices Act of 1990 (the SMDA).

**DATES:** Written comments by April 13, 1995. FDA proposes that any final regulation that may issue based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Robert A. Phillips, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850, 301–594–1212.

**SUPPLEMENTARY INFORMATION:**

### I. Background

The act, as amended by the 1976 amendments (Pub. L. 94–295) and the Safe Medical Devices Act of 1990 (Pub. L. 101–629), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval). Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments) are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendations for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device.

A device that is first offered in commercial distribution after May 28, 1976, and which FDA determines to be substantially equivalent to a device classified under this scheme, is classified into the same class as the device to which it is substantially equivalent. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807). A device that was not in commercial distribution prior to May 28, 1976, and that has not been found by FDA to be substantially equivalent to a legally marketed device, is classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking proceedings.

In 1980, when other obstetric and gynecological devices were classified (45 FR 12684 through 12720, February 26, 1980), FDA was not aware that transilluminators, also known as lightscanners or diaphanoscopes, for breast evaluation were preamendments devices, and inadvertently omitted them from the classification process. Based upon the recommendations the Obstetrics and Gynecological Devices Panel made during its January 11, 1991, meeting (Ref. 24), FDA is now proposing to classify the transilluminator for breast evaluation into class III, thereby requiring each manufacturer of the device to submit to FDA a PMA by a date to be set in a future regulation under section 515(b) of the act (21 U.S.C. 360e(b)). Specifically, a preamendments class III device may be commercially distributed without an approved PMA until 90 days after FDA issues a final rule requiring premarket approval of the device or 30 months after classification of the device under section 513 of the act, whichever is later. Each application must include sufficient valid scientific evidence to provide reasonable assurance that the device is safe and effective under the conditions of use prescribed,