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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 884**

[Docket No. 97N-0335]

**Obstetric and Gynecologic Devices; Reclassification and Classification of Medical Devices Used for In Vitro Fertilization and Related Assisted Reproduction Procedures; Technical Amendment**

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

**ACTION:** Final rule; technical amendment.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending its obstetrical and gynecological device regulations regarding assisted reproductive microscopes and microscope accessories. This action is being taken to ensure accuracy and clarity in the agency's regulations.

**EFFECTIVE DATE:** *(Insert date of publication in the Federal Register.)*

**FOR FURTHER INFORMATION CONTACT:** LaJuana D. Caldwell, Office of Policy (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7010.

**SUPPLEMENTARY INFORMATION:** FDA has discovered that an error was incorporated into the agency's obstetrical and gynecological devices regulations for assisted reproductive microscopes and microscope accessories. In an amendment to 21 CFR part 884, which added 21 CFR 884.6190 and published on September 10, 1998 (63 FR 48428), a sentence stating that the device is exempt from the premarket notification procedures was inadvertently included in paragraph (a) instead of paragraph (b). This document corrects that error. Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment is nonsubstantive.

**List of Subjects in 21 CFR Part 884**

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 884 is amended as follows:

**PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES**

1. The authority citation for 21 CFR part 884 continues to read as follows:

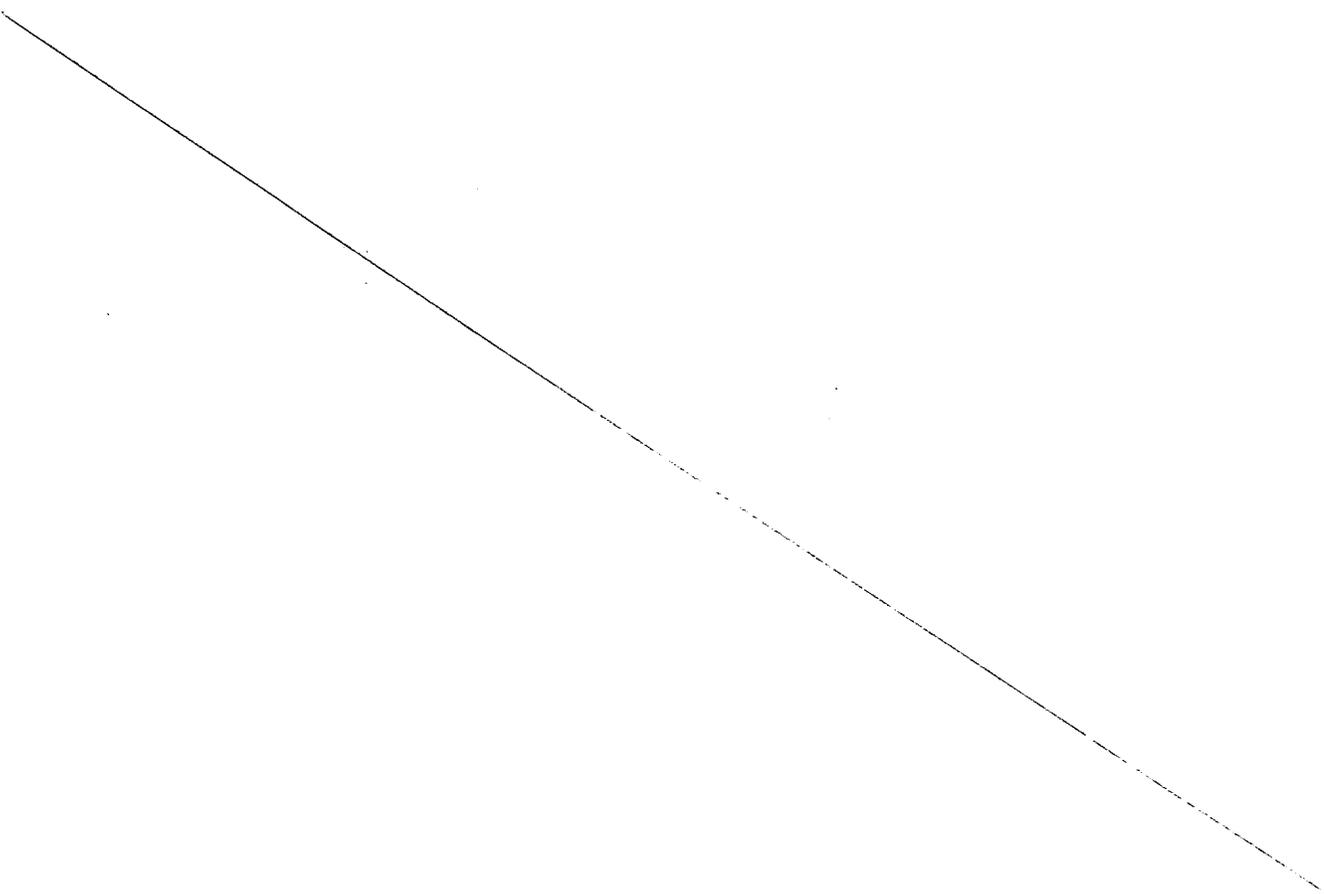
**Authority:** 21 CFR U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 884.6190 is amended by removing the last sentence in paragraph (a), and paragraph (b) is revised to read as follows:

**§ 884.6190 Assisted reproductive microscopes and microscope accessories.**

\* \* \* \* \*

(b) *Classification.* Class 1.



This device is exempt from the premarket notification procedures in subpart E of part 807 of chapter subject to limitation in § 884.9.

Dated: 4/4/99  
November 4, 1999

*Linda S. Kahan*

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Linda S. Kahan  
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Center for Devices and Radiological Health

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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*Michael W. Bell*