J–25 [Revised]

From the INT of the United States/Mexican Border and the Brownsville, TX, INT 221° radial via Brownsville; INT of the Brownsville 358° and the Corpus Christi, TX, 178° radials; Corpus Christi; INT of the Corpus Christi 311° and the San Antonio, TX, 174° radials; San Antonio; Centex, TX; Waco, TX; Ranger, TX; Tulsa, OK; Kansas City, MO; Des Moines, IA; Mason City, IA; Gopher, MN; Brainerd, MN; to Winnipeg, MB, Canada. The airspace within Canada is excluded. The airspace within Mexico is excluded.

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Issued in Washington, DC, on June 27, 2000.

Reginald C. Matthews,

Manager, Airspace and Rules Division

[FR Doc. 00–16915 Filed 7–3–00; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 97–ASO–18]

RIN 2120–AA66

Realignment and Establishment of VOR Federal Airways; KY and TN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This action corrects a final rule published in the **Federal Register** on June 2, 2000. The legal description of Federal Airway V–384 inadvertently listed incorrect radials. This action corrects that error.

EFFECTIVE DATE: July 5, 2000.

FOR FURTHER INFORMATION CONTACT: Terry Brown, Airspace and Rules Division, ATA–400, Office of Air Traffic Airspace Management, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION: On June 2, 2000, Airspace Docket No. 97–ASO–18, FR Doc. 00–13750, was published establishing V–384 between Livingston, TN, and Volunteer, TN. This rule included a legal description for V–384, which inadvertently listed incorrect radials. This action corrects this situation by omitting the radials in the legal description for V–384, thereby eliminating the error.

Correction to Final Rule

Accordingly, pursuant to the authority delegated to me, the legal description for V–384 as published in the **Federal Register** on June 2, 2000 (65 FR 35272); FR Doc. 00–13750, and incorporated by reference in 14 CFR 71.1, is corrected as follows:

§ 71.1 [Corrected]

On page 35273, the legal description for V–384 is corrected as follows:

Paragraph 6010(a)—Domestic VOR Federal Airways

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V–384—[Revised]

From Livingston, TN; to Volunteer, TN.

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Issued in Washington, DC, on June 27, 2000.

Reginald C. Matthews,

Manager, Airspace and Rules Division.

[FR Doc. 00–16914 Filed 7–3–00; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. 95N–0084]

Medical Devices; Effective Date of Requirement for Premarket Approval for a Class III Preamendments Obstetrical and Gynecological Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to require the filing of a premarket approval application (PMA) or a notice of completion of product development protocol (PDP) for a Group 1 preamendments class III device, the obstetric data analyzer intended to analyze data from fetal and maternal monitors during labor and to warn of possible fetal distress. The agency has summarized its findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to meet the statute's approval requirements and the benefits to the public from the use of the devices.

DATES: This rule is effective July 5, 2000.

FOR FURTHER INFORMATION CONTACT: Colin M. Pollard, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1180.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 6, 1994 (59 FR 23731), FDA issued a notice of availability of a preamendments class III devices strategy document. The strategy document set forth FDA's plans for implementing the provisions of section 515(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(i)) for preamendments class III devices for which FDA had not yet required premarket approval. FDA divided this universe of devices into three groups as referenced in the May 6, 1994, notice.

In the **Federal Register** of September 7, 1995 (60 FR 46718), FDA published a proposed rule to require the filing under section 515(b) of the act of a PMA or a notice of completion of a PDP for 43 preamendment class III devices, including the obstetric data analyzer. In accordance with section 515(b)(A)(2) of the act, FDA included in the preamble to the proposal the agency's tentative findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to meet the premarket approval requirements of the act, and the benefits to the public from use of the device. The September 7, 1995, proposed rule also provided an opportunity for interested persons to submit comments on the proposed rule and the agency's findings. Under section 515(b)(2)(B) of the act, FDA provided an opportunity for interested persons to request a change in the classification of the device based on new information relevant to its classification. Any petition requesting a change in the classification of the devices was required to be submitted by September 22, 1995. The comment period closed January 5, 1996.

FDA received one citizen petition requesting a change in the classification of the obstetrical data analyzer. FDA reviewed the petition, identified a deficiency in the petition, and issued a deficiency letter on March 7, 1996, to the petitioner. From the petitioner's response to the deficiency letter, it was apparent that the petitioner had misinterpreted the September 7, 1995, proposed rule because he believed that it was about another device and not the obstetrical data analyzer. In light of this petition, FDA has amended the identification of the device in § 884.2050(a) by changing the first two sentences to read as follows: ''An obstetric data analyzer (fetal status data analyzer) is a device used during labor to analyze electronic signal data obtained from fetal and maternal monitors. The obstetric data analyzer provides clinical diagnosis of fetal