Amendment Number 8, Effective Date: March 24, 2020.

Amendment Number 9, Effective Date: December 7, 2020.

Amendment Number 10, Effective Date: January 18, 2023.

SAR Submitted by: NAC International, Inc.

SAR Title: Final Safety Analysis Report for the MAGNASTOR® System.

Docket Number: 72–1031.

Certificate Expiration Date: February 4, 2029.

Model Number: MAGNASTOR®.

* * * * *

Dated: October 20, 2022.

For the Nuclear Regulatory Commission.

Daniel H. Dorman

Executive Director for Operations.

[FR Doc. 2022–24010 Filed 11–3–22; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 13

[Docket No.: FAA–2018–1051; Amdt. No.: 13–40A]

RIN 2120–AL00

Update to Investigative and Enforcement Procedures and Part 11; Correction

AGENCY: Federal Aviation Administration (FAA), U.S. Department of Transportation (DOT).

ACTION: Final rule; correction.

SUMMARY: On October 11, 2022, the FAA published a final rule titled ''Update to Investigative and Enforcement Procedures and Part 11; Technical Amendments.'' That document made technical amendments to the Update to Investigative and Enforcement Procedures final rule, which was published on October 1, 2021. The technical amendments rule inadvertently identified the Rulemaking Identification Number (RIN).

DATES: Effective November 4, 2022.

FOR FURTHER INFORMATION CONTACT: Cole R. Milliard, Office of the Chief Counsel, AGC–300, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone (202) 267–3452; email *Cole.Milliard@faa.gov,* or Jessica E. Kabaz-Gomez, Office of the Chief Counsel, AGC–300, Federal Aviation Administration, (202) 267–7395.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of October 11, 2022, in FR Doc. 2022–21354, on page 61232, in the first column, correct the RIN to read: RIN 2120–AL00.

Issued in Washington, DC, under the authority provided by 49 U.S.C. 106(f), 40101 note and 44807, on October 21, 2022.

Brandon Roberts,

Executive Director, Office of Rulemaking.

[FR Doc. 2022–23990 Filed 11–3–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0436; Airspace Docket No. 22–ASW–1]

RIN 2120–AA66

Amendment and Establishment of Air Traffic Service (ATS) Routes; South Central United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This action corrects a final rule published by the FAA in the **Federal Register** on October 27, 2022, that amends VHF Omnidirectional Range (VOR) Federal airways V–198, V–212, V–556, and V–558; amends Area Navigation (RNAV) route T–256; and establishes RNAV route T–466. In the new RNAV route T–466, the final rule identified the CHILD, TX, route point as a waypoint (WP) and the SEEDS, TX, route point as a Fix, in error. This action makes editorial corrections to the reference of the CHILD, TX, WP to change it to be reflected as a Fix and to the SEEDS, TX, Fix to change it to be reflected as a WP. These corrections are necessary to match the FAA National Airspace System Resource (NASR) database information.

DATES: Effective date 0901 UTC, December 29, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11G, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

History

The FAA published a final rule in the **Federal Register** (87 FR 65011; October 27, 2022), amending VOR Federal airways V–198, V–212, V–556, and V–558; amending RNAV route T–256; and establishing RNAV route T–466. Subsequent to publication, the FAA determined that the CHILD, TX, route point was inadvertently identified as a WP and the SEEDS, TX, route point was inadvertently identified as a Fix, in error. The correct route point references are the CHILD, TX, Fix and the SEEDS, TX, WP. This rule corrects those errors by changing the reference of the CHILD, TX, WP to the CHILD, TX, Fix; and the reference of the SEEDS, TX, Fix to the SEEDS, TX, WP.

These are editorial changes only to match the FAA NASR database information and do not alter the alignment of the affected T–466 route.

United States Area Navigation Routes are published in paragraph 6011 of FAA Order JO 7400.11G, dated August 19, 2022, and effective September 15, 2022, which is incorporated by reference in 14 CFR 71.1. The RNAV T-route listed in this document will be published subsequently in FAA Order JO 7400.11.

Correction to Final Rule

Accordingly, pursuant to the authority delegated to me, references to the CHILD, TX, WP and to the SEEDS, TX, Fix that are reflected in Docket No. FAA–2022–0436, as published in the **Federal Register** of October 27, 2022 (87 FR 65011), FR Doc. 2022–22164, are corrected as follows:

■ 1. On pages 65012 and 65013, correct the table for T–466 San Angelo, TX (SJT) to Sabine Pass, TX (SBI) [New] to read:

T–466 San Angelo, TX (SJT) to Sabine Pass, TX (SBI) [New]

San Angelo, TX (SJT)	VORTAC	(Lat. 31°22′29.84″ N, long. 100°27′17.53″ W)
CHILD, TX	FIX	(Lat. 31°03′41.17″ N, long. 100°27′40.62″ W)
Junction, TX (JCT)	VORTAC	(Lat. 30°35′52.88″ N, long. 099°49′02.93″ W)

BETTI, TX	FIX	(Lat. 29°57′54.97″ N, long. 098°03′23.98″ W)
MARCS, TX	FIX	(Lat. 29°53′52.04″ N, long. 097°51′40.70″ W)
SEEDS, TX	WP	(Lat. 29°39′31.94″ N, long. 097°14′58.66″ W)
LDRET, TX	WP	(Lat. 29°39′44.93″ N, long. 096°19′00.96″ W)
KEEDS, TX	WP	(Lat. 29°21′59.49″ N, long. 095°36′48.98″ W)
Scholes, TX (VUH)	VOR/DME	(Lat. 29°16′09.60″ N, long. 094°52′03.81″ W)
Sabine Pass, TX (SBI)	VOR/DME	(Lat. 29°41′12.19″ N, long. 094°02′16.72″ W)

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Issued in Washington, DC, on October 28, 2022.

Mark E. Gauch,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–23852 Filed 11–3–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2020–N–2297]

Microbiology Devices; Reclassification of Human Immunodeficiency Virus Viral Load Monitoring Tests

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final order to reclassify human immunodeficiency virus (HIV) viral load monitoring tests, postamendments class III devices with the product code MZF, into class II (special controls), subject to premarket notification. Through this final order, FDA is also adding a new device classification regulation along with special controls that are necessary to provide a reasonable assurance of safety and effectiveness for this device type. The final order reclassifies this device type from class III (premarket approval) to class II (special controls) and will reduce the regulatory burdens associated with these devices because manufacturers will no longer be required to submit a premarket approval application (PMA) for this device type but can instead submit a less burdensome premarket notification (510(k)) and receive clearance before marketing their device.

DATES: This order is effective December 5, 2022.

FOR FURTHER INFORMATION CONTACT: Myrna Hanna, Center for Biologics Evaluation and Review, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 72, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (Pub. L. 101–629), the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115), the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), the Medical Devices Technical Corrections Act (Pub. L. 108–214), the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), and the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), among other amendments, establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting 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 (general controls and special controls), and class III (general controls and premarket approval).

Section 513(a)(1) of the FD&C Act defines the three classes of devices. Class I devices are those devices for which the general controls of the FD&C Act (controls authorized by or under sections 501, 502, 510, 516, 518, 519, or 520 (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, or 360j) or any combination of such sections) are sufficient to provide reasonable assurance of safety and effectiveness; or those devices for which insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of safety and effectiveness or to establish special controls to provide such assurance, but because the devices are not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and do not present a potential unreasonable risk of illness or injury, are to be regulated by general controls (section 513(a)(1)(A) of the FD&C Act). Class II devices are those devices for which general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness and for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and other appropriate actions the Agency deems necessary to provide such assurance (section 513(a)(1)(B) of the FD&C Act). Class III devices are those devices for which insufficient information exists to determine that general controls and special controls would provide a reasonable assurance of safety and effectiveness, and are purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury (section 513(a)(1)(C) of the FD&C Act).

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices) are automatically classified by section 513(f)(1) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until: (1) FDA reclassifies the device into class I or class II, or (2) FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. FDA determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act and part 807 (21 CFR part 807), subpart E, of the regulations.

A postamendments device that has been initially classified in class III under section 513(f)(1) of the FD&C Act may be reclassified into class I or II under section 513(f)(3) of the FD&C Act. Section 513(f)(3) of the FD&C Act provides that FDA, acting by administrative order, can reclassify the device into class I or class II on its own initiative, or in response to a petition from the manufacturer or importer of the device. To change the classification of the device, the proposed new class must have sufficient regulatory controls to provide a reasonable assurance of the