| Country<br>* | Entity   |               | License requirement   | License review policy |        | Federal Register citation                     |
|--------------|--|---------------|---|-----------------------|--------|---|
|              | *  | *             | *   | *                     | *      | *   |
| RUSSIA       | *  | *             | *   | *                     | *      | *   |
|              | Aviatech Supply Ltd.,<br>lowing two aliases:<br>-Aviatech; and<br>-Aviatechexport Ltd.<br>630123, Aeroport St.<br>Floor, Novosibirsk, Ru | Build.1A, 3rd | For all items subject to the EAR. (See § 744.11 of the EAR)       | Presumption of o      | denial | 88 FR [INSERT FR PAGE<br>NUMBER]<br>3/30/2023 |
|              | Aviazapchast PLC, 48, Ivana Franko<br>Street, Moscow, 121351, Russia.  |               | For all items subject to<br>the EAR. (See § 744.11<br>of the EAR) |                       |        | 88 FR [INSERT FR PAGE<br>NUMBER ] 3/30/2023.  |
|              | *  | *             | * '   | *                     | *      |   |
| *            | *  | *             | *   | *                     | *      | *   |

#### Thea D. Rozman Kendler,

Assistant Secretary for Export Administration.

[FR Doc. 2023–06663 Filed 3–28–23; 4:15 pm]

BILLING CODE 3510-33-P

## SECURITIES AND EXCHANGE COMMISSION

#### 17 CFR Part 240

## General Rules and Regulations, Securities Exchange Act of 1934

CFR Correction

This rule is being published by the Office of the Federal Register to correct an editorial or technical error that appeared in the most recent annual revision of the Code of Federal Regulations.

■ In Title 17 of the Code of Federal Regulations, Part 240, revised as of April 1, 2022, in section 240.13e–100, reinstate the paragraphs at the end of the section following "Item 16. Exhibits" to read as follows:

§ 240.13e–100 Schedule 13E–3, Transaction statement under section 13(e) of the Securities Exchange Act of 1934 and Rule 13e–3 (§ 240.13e–3) thereunder.

Signature. After due inquiry and to the best of my knowledge and belief, I certify that the information set forth in this statement is true, complete and correct.

(Signature)

(Name and title)

(Date)

Instruction to Signature: The statement must be signed by the filing person or that person's authorized representative. If the statement is signed

on behalf of a person by an authorized representative (other than an executive officer of a corporation or general partner of a partnership), evidence of the representative's authority to sign on behalf of the person must be filed with the statement. The name and any title of each person who signs the statement must be typed or printed beneath the signature. See § 240.12b–11 with respect to signature requirements.

[FR Doc. 2023-06701 Filed 3-29-23; 8:45 am]

BILLING CODE 0099-10-P

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## **Food and Drug Administration**

#### 21 CFR Part 888

[Docket No. FDA-2021-N-0310] RIN 0910-AI32

## Medical Devices; Orthopedic Devices; Classification of Spinal Spheres for Use in Intervertebral Fusion Procedures

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

**ACTION:** Final rule.

SUMMARY: The Food and Drug
Administration (FDA or Agency) is
issuing a final rule to classify spinal
spheres for use in intervertebral fusion
procedures (an unclassified,
preamendments device) into class III for
which FDA is separately requiring the
filing of a premarket approval
application (PMA). FDA has determined
that general controls and special
controls together are insufficient to
provide reasonable assurance of safety
and effectiveness for this device.

**DATES:** This rule is effective May 1, 2023.

**ADDRESSES:** For access to the docket to read background documents or

comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this final rule, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

#### FOR FURTHER INFORMATION CONTACT:

Constance Soves, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1656, Silver Spring, MD 20993–0002, 301–796–6951, Constance.Soves@fda.hhs.gov.

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#### I. Executive Summary

## A. Purpose of the Final Rule

FDA is classifying spinal spheres for use in intervertebral fusion procedures (spinal spheres), which are unclassified, preamendments devices, into class III. A