PART 743—SPECIAL REPORTING AND NOTIFICATION

■ 3. The authority citation for 15 CFR part 743 is revised to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13637, 78 FR 16129, 3 CFR, 2014 Comp., p. 223; 78 FR 16129.

■ 4. Section 743.5(e) is amended by removing ''*bis.compliance@bis.doc.gov*'' and adding in its place ''mcd_*compliance@bis.doc.gov*.''

■ 5. Section 743.6 is added to read as follows:

§ 743.6 Prior notifications to Congress of exports of certain semiautomatic firearms.

(a) *General requirement.* Applications to export semiautomatic firearms controlled by ECCN 0A501.a will be notified to Congress as provided in this section before licenses for such items are issued, except as specified in paragraphs (a)(1) to (2) of this section.

(1) Exports of semiautomatic firearms controlled by ECCN 0A501.a to personnel and agencies of the U.S. Government under License Exception GOV (§ 740.11(b) of the EAR) do not require such notification.

(2) Exports of semiautomatic firearms controlled by ECCN 0A501.a for official use by an agency of NATO do not require such notification.

(b) *Notification criteria.* Unless excluded in paragraphs (a)(1) to (2) of this section, BIS will notify Congress prior to issuing a license authorizing the export of items to Mexico, South Africa, or Turkey or any other country not listed in Country Group A:5 or A:6 (see supplement no.1 to part 740 of the EAR) if the items are sold under a contract or are otherwise part of an export transaction that includes $4,000,000 or more of semiautomatic firearms controlled by ECCN 0A501.a.

(c) *License application information.* In addition to information required on the application, the exporter must include a copy of the signed contract or, if there is no contract, a written explanation from the applicant (including a statement of the value of the firearms controlled by ECCN 0A501.a to be exported) for any proposed export described in paragraph (b) of this section. License applications for semiautomatic firearms controlled by ECCN 0A501.a may include other nonautomatic firearms, shotguns, other 0x5zz items, or other items subject to the EAR, but the applicant must clearly identify the semiautomatic firearms controlled by ECCN 0A501.a. The applicant clearly distinguishing the semiautomatic firearms controlled by ECCN 0A501.a from any other items on the license application will assist BIS in assessing whether the license application requires congressional notification under this section and identifying the information that will need to be reported to Congress. Any activity intended to circumvent notification requirements is prohibited. Such devices include, but are not limited to, the splitting or structuring of contracts to avoid exceeding applicable notification dollar value limits described in paragraph (a) of this section.

(d) *Additional information.* For questions on this section, you may contact the Nuclear and Missile Technology Controls Division, Guns and Ammunition licensing group at *firearmsCN@bis.doc.gov*.

PART 748—APPLICATIONS (CLASSIFICATION, ADVISORY, AND LICENSE) AND DOCUMENTATION

■ 6. The authority citation for 15 CFR part 748 is revised to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 6, 2021, 86 FR 43901 (August 10, 2021).

■ 7. Supplement No. 2 to part 748 (Unique Application and Submission Requirements) is amended by adding paragraphs (aa) and (bb) to read as follows:

Supplement No. 2 to Part 748—Unique Application and Submission Requirements

* * * * *

(aa) ''*600 Series Major Defense Equipment.*'' For license applications that require prior notifications to Congress of exports of ''600 series major defense equipment'' pursuant to § 743.5, the exporter must include a copy of the signed contract (including a statement of the value of the ''600 Series Major Defense Equipment'' to be exported under the contract). (*See* § 743.5(d) of the EAR)

(bb) *Semiautomatic firearms controlled under ECCN 0A501.a.* For export license applications that require prior notifications to congress of exports of semiautomatic firearms controlled under ECCN 0A501.a under the criteria of § 743.6, the exporter must include a copy of the signed contract or, if there is no contract, a written explanation from the applicant (including a statement of the value of the firearms controlled by ECCN 0A501.a to be exported). License applications for semiautomatic firearms controlled by ECCN 0A501.a may include other nonautomatic firearms, shotguns, other 0x5zz items, or other items subject to the EAR, but the applicant must clearly identify the semiautomatic firearms controlled by ECCN 0A501.a.

Thea D. Rozman Kendler,

Assistant Secretary for Export Administration.

[FR Doc. 2022–11761 Filed 5–31–22; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 744

Control Policy: End-User and End-Use Based

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 15 of the Code of Federal Regulations, Parts 300 to 799, revised as of January 1, 2022, in supplement no. 4 to part 744, in the table under ''RUSSIA'', revise the entry for ''Kaliningradnefteprodukt OOO'' to read as follows:

SUPPLEMENT NO. 4 TO PART 744—ENTITY LIST

Country	Entity	License requirement	License review policy	**Federal Register** citation
*	*	*	*	*	*	*
RUSSIA	*	*	*	*	*	*

SUPPLEMENT NO. 4 TO PART 744—ENTITY LIST—Continued

Country	Entity	License requirement	License review policy	**Federal Register** citation
	Kaliningradnefteprodukt OOO, a.k.a., the following three aliases: —Kaliningradnefteprodukt LLC; —Limited Liability Company Kaliningradnefteproduct; and —LLC Kaliningradnefteproduct 22–b Komsomolskaya Ulitsa, Central District, Kaliningrad, Russia.	For all items subject to the EAR when used in projects specified in § 746.5 of the EAR.	Presumption of denial	83 FR 6952, 2/16/18. 83 FR 12479, 3/22/18.
*	*	*	*	*	*	*

[FR Doc. 2022–11614 Filed 5–31–22; 8:45 am]

BILLING CODE 099–10–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1225

Safety Standard for Hand-Held Infant Carriers

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 16 of the Code of Federal Regulations, Part 1000 to End, revised as of January 1, 2022, in § 1225.2, add ''email: *cpsc-os@cpsc.gov,*'' in the fifth sentence after the telephone number ''301–504–7479''.

[FR Doc. 2022–11615 Filed 5–31–22; 8:45 am]

BILLING CODE 0099–10–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2022–N–0713]

Medical Devices; Cardiovascular Devices; Classification of the Coronary Artery Disease Risk Indicator Using Acoustic Heart Signals

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the coronary artery disease risk indicator using acoustic heart signals into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the coronary artery disease risk indicator using acoustic heart signals' classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective June 1, 2022. The classification was applicable on November 24, 2020.

FOR FURTHER INFORMATION CONTACT: Kimberly Crowley, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2531, Silver Spring, MD, 20993–0002, 301–796–6017, *Kimberly.Crowley@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the coronary artery disease risk indicator using acoustic heart signals as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (see 21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order