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.
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[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]

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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