

TABLE 1—VIBRATOR FOR CLIMAX CONTROL OF PREMATURE EJACULATION RISKS AND MITIGATION MEASURES

Identified risk	Mitigation measures
Pain or Discomfort due to Misuse of Device	Labeling.
Burns	Electrical and Thermal Safety Testing Labeling.
Electrical Shock	Electrical Safety Testing Labeling.
Adverse Skin Reactions	Biocompatibility Testing.
Patient Injury due to Device Breakage or Failure	Mechanical Safety Testing Labeling.
Interference With Other Devices/Electrical Equipment	Electromagnetic Compatibility Testing Labeling.

FDA believes that the following special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness:

- The labeling must include specific instructions regarding the proper placement and use of the device.
- The portions of the device that contact the patient must be demonstrated to be biocompatible.
- Appropriate analysis/testing must demonstrate electromagnetic compatibility safety, electrical safety, and thermal safety of the device.
- Mechanical safety testing must demonstrate that the device will withstand forces encountered during use.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the vibrator for climax control of premature ejaculation they intend to market.

II. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information

found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801, regarding labeling have been approved under OMB control number 0910–0485.

IV. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>.

1. DEN130047: De Novo Request per 513(f)(2) from Auris Medtech Europe Ltd., dated November 21, 2013.
2. Amendment to De Novo Request from Auris Medtech Europe Ltd., dated June 17, 2014.

List of Subjects in 21 CFR Part 876

Medical devices.
Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 876 is amended as follows:

PART 876—GASTROENTEROLOGY—UROLOGY DEVICES

- 1. The authority citation for 21 CFR part 876 continues to read as follows:
Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.
- 2. Republish § 876.5025 to read as follows:

§ 876.5025 Vibrator for climax control of premature ejaculation.

(a) *Identification.* A vibrator for climax control of premature ejaculation is used for males who suffer from premature ejaculation. It is designed to increase the time between arousal and ejaculation using the stimulating

vibratory effects of the device on the penis.

(b) *Classification.* Class II (special controls). The special controls for this device are:

- (1) The labeling must include specific instructions regarding the proper placement and use of the device.
- (2) The portions of the device that contact the patient must be demonstrated to be biocompatible.
- (3) Appropriate analysis/testing must demonstrate electromagnetic compatibility safety, electrical safety, and thermal safety of the device.
- (4) Mechanical safety testing must demonstrate that the device will withstand forces encountered during use.

Dated: June 16, 2015.

Leslie Kux,
Associate Commissioner for Policy.
[FR Doc. 2015–15328 Filed 6–22–15; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2013–0103]

RIN 1625–AA08

Regattas and Marine Parades; Great Lakes Annual Marine Events

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce various special local regulations for annual regattas and marine parades in the Captain of the Port Detroit zone from 9 a.m. on June 26, 2015 through 7 p.m. on August 23, 2015. Enforcement of these regulations is necessary and intended to ensure safety of life on the navigable waters immediately prior to, during, and immediately after these regattas or marine parades. During the aforementioned period, the Coast Guard will enforce restrictions upon, and control movement of, vessels in a

specified area immediately prior to, during, and immediately after regattas or marine parades.

DATES: The regulations in 33 CFR 100.914, 100.915, 100.918, 100.919, and 100.920 will be enforced at specified dates and times between June 26, 2015 and August 23, 2015.

FOR FURTHER INFORMATION CONTACT: If you have questions on this document, call or email Petty Officer First Class Todd Manow, Prevention Department, U.S. Coast Guard Sector Detroit, 110 Mount Elliot Ave., Detroit MI, 48207; telephone (313)568-9580, email Todd.M.Manow@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the following special local regulations listed in 33 CFR part 100, Safety of Life on Navigable Waters, on the following dates and times, which are listed in chronological order:

(1) *§ 100.919 International Bay City River Roar, Bay City, MI.* This special local regulation will be enforced from 9 a.m. to 6 p.m. on June 26, 27, and 28, 2015. A regulated area is established to include all waters of the Saginaw River bounded on the north by the Liberty Bridge, located at 43°36.3' N, 083°53.4' W, and bounded on the south by the Veterans Memorial Bridge, located at 43°35.8' N, 083°53.6' W. In case of rain on any of the race days, this special local regulation may be enforced an additional day on June 29, 2015 from 9 a.m. until 6 p.m.

(2) *§ 100.920 Tug Across the River, Detroit, MI.* This special local regulation will be enforced from 6 p.m. to 6:45 p.m. on July 10, 2015. A regulated area is established to include all waters of the Detroit River, Detroit, Michigan, bounded on the south by the International boundary, on the west by 083°03' W, on the east by 083°02' W, and on the north by the U.S. shoreline. This position is located on the Detroit River in front of Hart Plaza, Detroit, MI.

(3) *§ 100.914 Trenton Rotary Roar on the River, Trenton, MI.* This special local regulation will be enforced from 8 a.m. to 8 p.m. on July 17, 18, and 19, 2015. The regulated area is established to include all waters of the Detroit River, Trenton, Michigan, bounded by an east/west line beginning at a point of land at the northern end of Elizabeth Park in Trenton, MI, located at position 42°8.2' N; 083°10.6' W, extending east to a point near the center of the Trenton Channel located at position 42°8.2' N; 083°10.4' W, extending south along a north/south line to a point at the Grosse Ile Parkway Bridge located at position 42°7.7' N; 083°10.5' W, extending west along a line bordering the Grosse Ile Parkway Bridge to a point on land

located at position 42°7.7' N; 083°10.7' W, and along the shoreline to the point of origin. This area is in the Trenton Channel between Trenton and Grosse Isle, MI.

(4) *§ 100.915 St. Clair River Classic Offshore Race, St. Clair, MI.* This special local regulation will be enforced from 10 a.m. to 7 p.m. each day from July 20, 2015 through July 26, 2015. A regulated area is established to include all waters of the St. Clair River, St. Clair, Michigan, bounded by latitude 42°52'00" N to the north; latitude 42°49'00" N to the south; the shoreline of the St. Clair River on the west; and the international boundary line on the east.

Special Local Regulations:

(1) In accordance with § 100.901, entry into, transiting, or anchoring within these regulated areas is prohibited unless authorized by the Coast Guard patrol commander (PATCOM). The PATCOM may restrict vessel operation within the regulated area to vessels having particular operating characteristics.

(2) Vessels permitted to enter this regulated area must operate at a no wake speed and in a manner that will not endanger race participants or any other craft.

(3) The PATCOM may direct the anchoring, mooring, or movement of any vessel within this regulated area. A succession of sharp, short signals by whistle or horn from vessels patrolling the area under the direction of the PATCOM shall serve as a signal to stop. Vessels so signaled shall stop and shall comply with the orders of the PATCOM. Failure to do so may result in expulsion from the area, a Notice of Violation for failure to comply, or both.

(4) If it is deemed necessary for the protection of life and property, the PATCOM may terminate at any time the marine event or the operation of any vessel within the regulated area.

(5) In accordance with the general regulations in § 100.35 of this part, the Coast Guard will patrol the regatta area under the direction of a designated Coast Guard Patrol Commander (PATCOM). The PATCOM may be contacted on Channel 16 (156.8 MHz) by the call sign "Coast Guard Patrol Commander."

(6) The rules in this section shall not apply to vessels participating in the event or to government vessels patrolling the regulated area in the performance of their assigned duties.

This document is issued under authority of 33 CFR 100.35 and 5 U.S.C. 552(a). If the Captain of the Port determines that any of these special local regulations need not be enforced

for the full duration stated in this document, he may suspend such enforcement and notify the public of the suspension via a Broadcast Notice to Mariners.

Dated: June 8, 2015.

Scott B. Lemasters,

Captain, U. S. Coast Guard, Captain of the Port Detroit.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2015-0496]

RIN 1625-AA00

Safety Zone; Black River Kayak-a-thon; Black River, Lorain, OH

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on Black River, Lorain, OH. This safety zone is intended to restrict vessels from a portion of the Black River during the Black River Kayak-a-thon. This temporary safety zone is necessary to protect participants and mariners from the navigational hazards associated with a paddle sport regatta.

DATES: This rule is effective from 7:45 a.m. until 2:15 p.m. on June 27, 2015.

ADDRESSES: Documents mentioned in this preamble are part of docket [USCG-2015-0496]. To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type the docket number in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12-140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call LT Stephanie Pitts, Chief of Waterways Management, U.S. Coast Guard Marine Safety Unit Cleveland; telephone 216-937-0128. If you have questions on viewing the docket, call Ms. Cheryl Collins, Program Manager, Docket Operations, telephone 202-366-9826 or 1-800-647-5527.