philosophy and principles identified in the Executive Order. In addition, the reclassification action is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order. The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of the device from class III to class II will relieve manufacturers of the cost of complying with the premarket approval requirements in section 515 of the act. Because reclassification will reduce regulatory costs with respect to this device, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace at lower costs. The agency therefore certifies that this reclassification action will not have a significant economic impact on a substantial number of small entities. In addition, this reclassification action will not impose costs of $100 million or more on either the private sector or state, local, and tribal governments in the aggregate, and therefore a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

VI. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no information that is subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995. The special controls do not require the respondent to submit additional information to the public. Therefore, no burden is placed on the public.

VII. References

The following references have been placed on display in the Dockets Management Branch, 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.

1. P840008/S24, MFL 5000 Lithotripter, Dornier Medical Systems, Inc., July 3, 1991.

2. P840008/S26, MFL 9000 Lithotripter, Dornier Medical Systems, Inc., August 12, 1991.

3. Summary of Safety and Effectiveness, P890013, Piezolith Lithotripter, Model 2300, Richard Wolf Medical Instruments Corp., September 9, 1991.

4. Summary of Safety and Effectiveness, P880042, LT.01 Lithotripter, EDAP International Corp., December 12, 1991.

5. Summary of Safety and Effectiveness, TP890006, Therasonic Lithotripsy Treatment System, Diasonics, Inc., December 20, 1991.

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. Section 876.5990 is added to subpart F to read as follows:

§ 876.5990 Extracorporeal shock wave lithotripter.

(a) *Identification.* An extracorporeal shock wave lithotripter is a device that focuses ultrasonic shock waves into the body to noninvasively fragment urinary calculi within the kidney or ureter. The primary components of the device are a shock wave generator, high voltage generator, control console, imaging/localization system, and patient table. Prior to treatment, the urinary stone is targeted using either an integral or stand-alone localization/imaging system. Shock waves are typically generated using electrostatic spark discharge (spark gap), electromagnetically repelled membranes, or piezoelectric crystal arrays, and focused onto the stone with either a specially designed reflector, dish, or acoustic lens. The shock waves are created under water within the shock wave generator, and are transferred to the patient's body using an appropriate acoustic interface. After the stone has been fragmented by the focused shock waves, the fragments pass out of the body with the patient's urine.

(b) *Classification.* Class II (special controls) (FDA guidance document: ''Guidance for the Content of Premarket Notifications (510(k)'s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi.'')

Dated: July 12, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD05–00–030]

Special Local Regulations for Marine Events; Patapsco River, Baltimore, Maryland

AGENCY: Coast Guard, DOT.

ACTION: Notice of implementation.

SUMMARY: The Coast Guard is implementing the special local regulations found at 33 CFR 100.515 during the Defender's Day fireworks display to be held September 9, 2000, on the Patapsco River at Baltimore, Maryland. These special local regulations are necessary to control vessel traffic due to the confined nature of the waterway and expected vessel congestion during the fireworks display. The effect will be to restrict general navigation in the regulated area for the safety of spectators and vessels transiting the event area.

EFFECTIVE DATES: 33 CFR 100.515 is effective from 5:30 p.m. to 11 p.m. on September 9, 2000.

FOR FURTHER INFORMATION CONTACT: Chief Warrant Officer R. L. Houck, Marine Events Coordinator, Commander, Coast Guard Activities Baltimore, 2401 Hawkins Point Road, Baltimore, MD 21226–1971, (410) 576–2674.

SUPPLEMENTARY INFORMATION: The City of Baltimore will sponsor the Defender's Day fireworks display on September 9, 2000 on the Patapsco River, Baltimore, Maryland. The fireworks display will be launched from a barge positioned within the regulated area. In order to ensure the safety of spectators and transiting vessels, 33 CFR 100.515 will be in effect for the duration of the event. Under provisions of 33 CFR 100.515, a vessel may not enter the regulated area unless it receives permission from the Coast Guard Patrol Commander. Spectator vessels may anchor outside the regulated area but may not block a navigable channel. Because these restrictions will be in effect for a limited period, they should not result in a significant disruption of maritime traffic.

Dated: July 20, 2000.

J. E. Shkor,

Vice Admiral, U.S. Coast Guard, Commander, Fifth Coast Guard District.

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