

options that would minimize any significant impact of a rule on small entities. Reclassification of the device from class III to class II has relieved all manufacturers of the device of the cost of complying with the premarket approval requirements in section 515 of the act (21 U.S.C. 360e). Because reclassification has reduced regulatory costs with respect to this device, no significant economic impact has been imposed on any small entities, and it may have permitted small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that this final rule does not have a significant economic impact on a substantial number of small entities. In addition, this final rule 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 or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

List of Subjects in 21 CFR Part 878

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 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

1. The authority citation for 21 CFR part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Section 878.4495 is added to subpart E to read as follows:

§ 878.4495 Stainless steel suture.

(a) *Identification.* A stainless steel suture is a needled or unneedled nonabsorbable surgical suture composed of 316L stainless steel, in USP sizes 12–0 through 10, or a substantially equivalent stainless steel suture, intended for use in abdominal wound closure, intestinal anastomosis, hernia repair, and sternal closure.

(b) *Classification.* Class II (special controls).

Dated: March 29, 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 117

[CGD07–00–022]

RIN 2115–AE47

Drawbridge Operation Regulations; Wappoo Creek (ICW), Charleston, SC

AGENCY: Coast Guard, DOT.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: Notice is hereby given that the Commander, Seventh Coast Guard District has approved a temporary deviation from the regulations governing the operation of the Folly Road (SC Route 171) drawbridge across the Atlantic Intracoastal Waterway, mile 470.8, Charleston, Charleston County, South Carolina. This deviation allows the drawbridge owner or operator to open only a single leaf of the drawbridge, and requires one hour advance notification to accommodate a request for a full double-leaf opening. This temporary schedule allows the bridge owner to safely conduct necessary repairs to the drawbridge.

DATES: This deviation is effective from March 28, 2000 to May 16, 2000.

FOR FURTHER INFORMATION CONTACT: Mr. Brodie Rich, Project Manager, Seventh Coast Guard District, Bridge Section at (305) 536–5117.

SUPPLEMENTARY INFORMATION: The Folly Road drawbridge across the Atlantic Intracoastal Waterway at Charleston, has a vertical clearance of 33 feet above mean high water (MHW) and 38 feet above mean low water (MLW) measured at the fenders in the closed position. On February 27, 2000, Coastal Marine Construction, Incorporated, the contractor representing the drawbridge owner, requested a deviation from the current operating regulation in 33 CFR 117.5 which requires drawbridge to open promptly and fully when a request to open is given. This temporary deviation was requested to allow necessary repairs to the drawbridge in a critical time sensitive manner. The contractor has advised us that the drawbridge is likely to suffer failure of operation, which would increase the intensity and length of time in order to complete the necessary repairs.

The District Commander has granted a temporary deviation from the operating requirements listed in 33 CFR 117.5 for the purpose of conducting repairs to the drawbridge. Under this deviation, the Folly Road (SC Route 171) Drawbridge need only open one

leaf of the drawbridge unless one hour advance notification is provided by the vessel operator to the drawbridge tender which would allow a full double-leaf opening. The deviation is effective for a period of 50 days beginning on March 28, 2000 and ending on May 16, 2000.

Dated: March 21, 2000.

T.W. Allen,

Rear Admiral, U.S. Coast Guard Commander, Seventh Coast Guard District.

[FR Doc. 00–9220 Filed 4–12–00; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[FRL–6566–9]

Finding of Failure To Submit a Required State Implementation Plan for Carbon Monoxide; Spokane, WA

AGENCY: Environmental Protection Agency (EPA).

ACTION: Finding of failure to submit.

SUMMARY: EPA is taking final action in making a finding, under the Clean Air Act (CAA or Act), that Washington failed to make a carbon monoxide (CO) nonattainment area State Implementation Plan (SIP) submittal required for Spokane under the Act. Under certain provisions of the Act, states are required to submit SIPs providing for, among other things, reasonable further progress and attainment of the CO National Ambient Air Quality Standards (NAAQS) in areas classified as serious. The deadline for submittal of this plan for Spokane was October 13, 1999. This action triggers the 18-month time clock for mandatory application of sanctions and 2-year time clock for a Federal Implementation Plan (FIP) under the Act. This action is consistent with the CAA mechanism for assuring SIP submissions.

EFFECTIVE DATE: This action is effective as of April 13, 2000.

ADDRESSES: Written comments should be addressed to: Ms. Debra Suzuki, Office of Air Quality (OAQ–107), EPA, 1200 Sixth Avenue, Seattle, Washington 98101.

FOR FURTHER INFORMATION CONTACT: Christi Lee, Office of Air Quality (OAQ), U.S.EPA, Region 10, Washington Operations Office, 300 Desmond Drive SE, Suite 102, Lacey, Washington, 98503, Telephone (360) 753–9079.

SUPPLEMENTARY INFORMATION: