

immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for some SIAP amendments may require making them effective in less than 30 days. For the remaining SIAPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs contained in the amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Approach Procedures (TERPs). In developing these SIAPs, the TERPs criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs is unnecessary, impracticable, and contrary to the public interest and, where applicable, that good cause exists for making some SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Approaches, Standard instrument, Incorporation by reference.

Issued in Washington, DC on November 10, 1989.

Daniel C. Beaudette,
Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, part 97 of the Federal Aviation Regulations (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures, effective at 0901 g.m.t. on the dates specified, as follows:

PART 97—[AMENDED]

1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 1348, 1354(a), 1421, and 1510; 49 U.S.C. 106(g) (revised Pub. L. 97-449, January 12, 1983; and 14 CFR 11.49(b)(2)).

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, ISMLS, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, identified as follows:

Effective January 11, 1990

Audubon, IA—Audubon County, NDB RWY 32, Amdt. 3
Cedar Rapids, IA—Cedar Rapids Muni, RNAV RWY 13, Amdt. 8
Coldwater, MI—Branch County Memorial, VOR RWY 6, Amdt. 3
Coldwater, MI—Branch County Memorial, VOR/DME RWY 24, Amdt. 3
Fremont, MI—Fremont Muni, VOR RWY 38, Amdt. 6
Fremont, MI—Fremont Muni, VOR-A, Amdt. 10
Camdenton, MO—Camdenton Memorial, VOR-A, Amdt. 2
Lewiston, MT—Lewiston Muni, VOR RWY 7, Amdt. 13
Imperial, NE—Imperial Muni, NDB RWY 31, Amdt. 1
Reidsville, NC—Rockingham County NC Shiloh, VOR/DME-A, Amdt. 7
Reidsville, NC—Rockingham County NC Shiloh, SDF RWY 31, Amdt. 2
Reidsville, NC—Rockingham County NC Shiloh, NDB RWY 31, Amdt. 3
Reidsville, NC—Rockingham County NC Shiloh, RNAV RWY 31, Amdt. 3
Marion, OH—Marion Muni, VOR RWY 24, Amdt. 5, Cancelled
Marion, OH—Marion Muni, VOR-A, Orig.
Marion, OH—Marion Muni, NDB RWY 12, Amdt. 4
Klamath Falls, OR—Klamath Falls International, VOR/DME or TACAN RWY 32, Amdt. 3
Sparta, TN—Sparta-White County, SDF RWY 4, Amdt. 2
Sparta, TN—Sparta-White County, NDB RWY 4, Amdt. 2
Milwaukee, WI—Lawrence J. Timmerman, VOR RWY 4L, Amdt. 7
Milwaukee, WI—Lawrence J. Timmerman, VOR RWY 15L, Amdt. 12
Milwaukee, WI—Lawrence J. Timmerman, LOC RWY 15L, Amdt. 4

Effective December 14, 1989

Dubuque, IA—Dubuque Regional, RNAV RWY 36, Amdt. 4, Cancelled
Osage Beach, MO—Linn Creek-Grand Glaize Meml, VOR RWY 32, Amdt. 3
Greenville, NC—Pitt-Greenville, NDB RWY 19, Amdt. 12
Upper Sandusky, OH—Wyandot County, VOR-A, Amdt. 3
Aiken, SC—Aiken Muni, NDB RWY 24, Amdt. 8

Effective November 7, 1989

Gunnison, CO—Gunnison County, VOR-A, Amdt. 7

Effective November 6, 1989

Islip, NY—Long Island Mac Arthur, NDB RWY 6, Amdt. 17

Islip, NY—Long Island Mac Arthur, ILS RWY 6, Amdt. 20

[FR Doc. 89-27404 Filed 11-21-89; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. 86P-0426]

Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented or Nonporous Uncemented Prosthesis; Announcement of Reclassification

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has issued an order in the form of a letter to a petitioner reclassifying the hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, and substantially equivalent devices of this generic type, from class III (premarket approval) into class II (performance standards). The order is being codified in the Code of Federal Regulations as specified herein.

EFFECTIVE DATES: The reclassification was effective December 5, 1988. The rule becomes effective December 22, 1989.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ-84), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4874.

SUPPLEMENTARY INFORMATION: On October 15, 1986, Protek, Inc., submitted to FDA under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)) and 21 CFR 860.120, a petition requesting reclassification of the hip joint metal/ceramic/polymer semi-constrained cemented or uncemented prosthesis excluding the ceramic acetabular cup from class III into class II. Consistent with the act and regulations, the agency referred the petition to the Orthopedic and Rehabilitation Devices Panel (the Panel). On October 31, 1986, at an open public meeting, the Panel recommended that FDA reclassify the generic type of device from class III to class II.

On May 27, 1988 (53 FR 19340), FDA published a notice of the Panel recommendation and invited interested persons to submit comments by July 26, 1988. Three comments were submitted.

Summaries of the comments and agency responses were included in the order to the petitioner of December 5, 1988. A copy of the order is available for public examination in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857, under the docket number found in brackets in the heading of this rule.

On December 5, 1988, FDA sent Protek, Inc., a letter (order) reclassifying the hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, and substantially equivalent devices of this generic type, from class III into class II.

Accordingly, as required by 21 CFR 860.134(b)(7) of the regulations, FDA is announcing the reclassification of the generic type of device from class III into class II. In addition, FDA is amending part 888 of title 21 of the Code of Federal Regulations to include the classification of the generic type of device.

After considering the economic consequences of approving this reclassification, FDA certifies that this final rule requires neither a regulatory impact analysis as specified in Executive Order 12291; nor a regulatory flexibility analysis as defined in the Regulatory Flexibility Act (Pub. L. 96-354). Approval of this petition will not have a significant economic impact on a substantial number of small entities. The petitioner and all future manufacturers of substantially equivalent hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis devices will be relieved of the costs of complying with the premarket approval requirement in section 515 of the act (21 U.S.C. 360e).

There are no offsetting costs that the petitioner or other manufacturers would incur from reclassification into class II other than those associated with meeting a standard once established. The magnitude of the economic savings attributable to this petition is dependent upon the number of premarket approval studies that the petitioner would have conducted and the number of future competitors satisfying the same requirements. Neither of these parameters can be reliably calculated to permit quantification of the economic savings.

List of Subjects in 21 CFR Part 888

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, chapter I of title 21 of the Code of Federal Regulations is amended in part 888 as follows:

PART 888—ORTHOPEDIC DEVICES

1. The authority citation for 21 CFR part 888 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. Section 888.3353 is added to subpart D to read as follows:

§ 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.

(a) *Identification.* A hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis is a device intended to be implanted to replace a hip joint. This device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. The two-part femoral component consists of a femoral stem made of alloys to be fixed in the intramedullary canal of the femur by impaction with or without use of bone cement. The proximal end of the femoral stem is tapered with a surface that ensures positive locking with the spherical ceramic (aluminum oxide, Al₂O₃) head of the femoral component. The acetabular component is made of ultra-high molecular weight polyethylene or ultra-high molecular weight polyethylene reinforced with nonporous metal alloys, and used with or without bone cement.

(b) *Classification.* Class II.

Dated: November 3, 1989.

Alan L. Hoeting,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 89-27375 Filed 11-21-89; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD 05-89-5105]

Special Local Regulations for Marine Events; Holidays in the City Boat Parade; Town Point, Elizabeth River, Norfolk, VA

AGENCY: Coast Guard, DOT.

ACTION: Notice of implementation of 33 CFR 100.501.

SUMMARY: This notice implements 33 CFR 100.501 for the Holiday in the City Boat Parade and Fireworks Display. The event will consist of a boat parade with approximately 75 vessels and a fireworks display at the conclusion of the parade. The regulations in 33 CFR

100.501 are needed to control vessel traffic within the immediate vicinity of the event due to the confined nature of the waterway and the expected congestion at the time of the event. The regulations restrict general navigation in the area for the safety of life and property on the navigable waters during the event.

EFFECTIVE DATE: The regulations in 33 CFR 100.501 are effective from 5 p.m. to 9 p.m., November 25, 1989.

FOR FURTHER INFORMATION CONTACT: Mr. Stephen Phillips, Chief, Boating Affairs Branch, Boating Safety Division, Fifth Coast Guard District, 431 Crawford Street, Portsmouth, Virginia 23704-5004, (804) 398-6204.

Drafting Information

The drafters of this notice are QM1 Kevin R. Connors, project officer, Boating Affairs Branch, Boating Safety Division, Fifth Coast Guard District, and Lieutenant Steven M. Fitten, project attorney, Fifth Coast Guard District Legal Staff.

Discussion of Regulation

The Downtown Norfolk Council submitted an application dated September 6, 1989 to hold the Holidays in the City Boat Parade and Fireworks Display. The boat parade will be held in the Elizabeth River in the Town Point area between the Banana Landmass and the Berkley Bridge. The fireworks display will be launched from the Banana Landmass, Town Point Park, Norfolk, Virginia, and will burst over the Elizabeth River. Since many spectator vessels are expected to be in the area to watch the boat parade and fireworks display, the regulations in 33 CFR 100.501 are being implemented for these events. The waterway will be closed during the fireworks display. Since the waterway will not be closed for an extended period, commercial traffic should not be severely disrupted.

In addition to regulating the area for the safety of life and property, this notice of implementation also authorizes the Patrol Commander to regulate the operation of the Berkley drawbridge in accordance with 33 CFR 117.1007, and authorizes spectators to anchor in the special anchorage areas described in 33 CFR 110.72aa. The implementation of 33 CFR 100.501 also implements regulations in 33 CFR 110.72aa and 117.1007. 33 CFR 110.72aa establishes the spectator anchorages in 33 CFR 100.501 as special anchorage areas under Inland Navigation Rule 30, 33 U.S.C. 2030(g). 33 CFR 117.1007 closes the draw of the Berkley Bridge to vessels during and for

one hour before and after the effective period under 33 CFR 100.501, except that the Coast Guard Patrol Commander may order that the draw be opened for commercial vessels.

These regulations are implemented by publication of this implementing notice in the *Federal Register* and a notice in the Local Notice to Mariners.

Dated: November 15, 1989.

P.A. Welling,

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

[FR Doc. 89-27431 Filed 11-21-89; 8:45 am]

BILLING CODE 4910-14-M

33 CFR Part 100

[OGD 05-89-5104]

Special Local Regulations for Marine Events; Sixth Annual Wrightsville Beach Holiday Flotilla; Banks Channel, Motts Channel, Intracoastal Waterway, Wrightsville and Wrightsville Beach, NC

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: Special local regulations are being adopted for the Sixth Annual Wrightsville Beach Holiday Flotilla. The event will be held in a section of Banks Channel between Wrightsville Channel Daybeacon 10 (LLNR 28025) and State Route 76 causeway bridge, in Motts Channel from Wrightsville Channel Daybeacon 14 (LLNR 28040) to Wrightsville Channel Daybeacon 25 (LLNR 28080) and the Intracoastal Waterway from Wrightsville Channel Daybeacon 25 (LLNR 28080) to the State Route 74-76 highway bridge. After the parade a fireworks display will be held within the regulated area. The special local regulations will govern vessel activities during the event. The regulations are necessary to control vessel traffic within the immediate area due to the confined nature of the waterway, and expected spectator craft congestion during the event.

EFFECTIVE DATE: These regulations are effective from 4 p.m. to 11 p.m., November 25, 1989. If inclement weather causes the postponement of the event, the regulations are effective from 4 p.m. to 11 p.m., November 26, 1989.

FOR FURTHER INFORMATION CONTACT: QM1 Kevin R. Connors, Boating Affairs Branch, Boating Safety Division, Fifth Coast Guard District, 431 Crawford Street, Portsmouth, Virginia 23704-5004 (804) 398-6204.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 553, a notice of proposed rulemaking has not been

published for these regulations and good cause exists for making them effective less than 30 days from the date of *Federal Register* publication. Adherence to normal rulemaking procedures would not have been possible. Specifically, the sponsor's application to hold the event was not received in this office until October 30, 1989, leaving insufficient time to publish a notice of proposed rulemaking in advance of the event.

Drafting Information

The drafters of this notice are QM1 Kevin R. Connors, project officer, Boating Affairs Branch, Fifth Coast Guard District, and Lieutenant Steven M. Fitten, project attorney, Fifth Coast Guard District Legal Staff.

Discussion of Regulations

The Greater Wilmington Chamber of Commerce submitted an application on October 20, 1989 to hold the Sixth Annual Wrightsville Beach Holiday Flotilla Boat Parade and Fireworks Display. The boat parade will consist of approximately 50 vessels sailing a course beginning at the State Route 74-76 highway bridge over the Intracoastal Waterway and heading southwest to Wrightsville Channel Daybeacon 25 (LLNR 28080), turning southeast through Motts Channel to Wrightsville Channel Daybeacon 14 (LLNR 28040), turning northeast into Banks Channel to the State Route 76 causeway bridge, turning to the southwest through Banks Channel to Wrightsville Channel Daybeacon 10 (LLNR 28025) and then returning to Wrightsville Channel Daybeacon 25 (LLNR 28080) via Banks Channel and Motts Channel. The fireworks will be launched from an unnamed island west of Wrightsville Channel Daybeacon 14 (LLNR 28040). Any fallout from the fireworks display will be within the regulated area. These regulations are necessary to control spectator craft and to provide for the safety of life and property on navigable waters during the event. Because commercial vessels will be permitted to transit the regulated area between events, commercial traffic should not be severely disrupted.

Economic Assessment and Certification

These regulations are not considered major under Executive Order 12291 on Federal Regulation nor significant under Department of Transportation regulatory policies and procedures (44 FR 11034; February 26, 1979). The economic impact is expected to be so minimal that a full regulatory evaluation is unnecessary. Because of this minimal impact, the Coast Guard certifies that these regulations will not have a significant

economic impact on a substantial number of small entities.

Federalism Assessment

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that the final rule does not raise sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environmental Impact

This final rule has been thoroughly reviewed by the Coast Guard and has been determined to be categorically excluded from further environmental documentation in accordance with section 2.B.2.c of Commandant Instruction M16475.1B. A Categorical Exclusion Determination statement has been prepared and has been placed in the rulemaking docket.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water).

Final Regulations

In consideration of the foregoing, part 100 of title 33, Code of Federal Regulations is amended as follows:

1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233; 49 CFR 1.46 and 33 CFR 100.35.

2. A temporary § 100.35-5104 is added to read as follows:

§ 100.35-5104 Intracoastal Waterway, Motts Channel, Banks Channel, Wrightsville and Wrightsville Beach, North Carolina.

(a) *Definitions*—(1) *Regulated area*. The waters of, and adjacent to Banks Channel between Wrightsville Channel Daybeacon 10 (LLNR 28025) located at 34°11'20.0" North, longitude 77°48'48.5" West, and State Route 76 causeway bridge with its center located at 34°12'33.0" North, longitude 77°47'51.0" West, Motts Channel from Wrightsville Channel Daybeacon 14 (LLNR 28040) located at 34°12'18.5" North, longitude 77°48'09.0" West to Wrightsville Channel Daybeacon 25 (LLNR 28080) located at 34°12'51.0" North, longitude 77°48'54.0" West and the Intracoastal Waterway from Wrightsville Channel Daybeacon 25 (LLNR 28080) to the State Route 74-76 highway bridge with its center located at 34°13'05.0" North, longitude 77°48'47.0" West.

(2) *Coast Guard Patrol Commander*. The Coast Guard Patrol Commander is a commissioned, warrant, or petty officer who has been designated by the Commander, Coast Guard Group Fort Macon.