

identical) to establish whether, under a launch services agreement with NASA, the article (i) is to be launched into space; or (ii) is a spare part to an article to be launched into space; or (iii) is necessary and uniquely associated support equipment for use in connection with a launch into space. Identify the launch services agreement, launch vehicle, and launch date(s).

(4) If the article is represented to be necessary and uniquely associated support equipment for use in connection with a launch into space, explain, with respect to each such article or each such class of articles to be imported, (i) why it is necessary and unique; and (ii) if the article may be used in connection with an activity other than a launch into space, whether or not it is intended to be so used. If it may be used in such other activity, NASA shall require of non-U.S. Government agencies, as a condition to obtaining duty-free entry under this subpart, that the customer agree in the relevant launch agreement not to use or in any manner dispose of those articles in the United States other than in connection with a launch into space; and

(5) The anticipated date of entry and port of entry for each article. If the article is to be transported in bond from the port of arrival to another port of entry in the United States, identify both ports.

(c) The signed certificate and its attachment will be forwarded to the NASA Installation responsible for duty-free entry of the materials. The procedures specified in 19 CFR 10.102 will be followed by the NASA Installation in obtaining duty-free entry at the Customs port of entry. The NASA Installation should ensure that, at the time the articles are to be released after Customs entry, the custody of the imported articles is transferred directly from the carrier or from the U.S. Customs Service to the NASA launch service customer or its agent.

(d) If articles procured under contract by NASA are imported prior to compliance with these procedures and it is essential that the articles be released from Customs custody prior to such compliance, the procedures outlined in 19 CFR 10.101 may be followed by cognizant NASA officials to secure the release of the articles from Customs custody. To the extent applicable, the procedures in § 1217.104 of this part shall be followed when time permits to obtain duty-free entry for the articles released from Customs custody.

#### § 1217.105 Necessary and uniquely associated support equipment.

The NASA certifying officer should consider the following criteria in determining whether an article is necessary and uniquely associated support equipment for use in connection with a launch into space. Applicability of one or more of the following nonexclusive criteria lends support to the conclusion that the article is necessary and uniquely associated support equipment.

(a) The article has been designed and manufactured solely to support (1) the launch or return of a launch vehicle, spacecraft (including Space Station), or payload; or (2) the operations or use in space of a launch vehicle, spacecraft (including Space Station), or payload.

(b) A standard article has been modified in a substantial and extraordinary way, considering its physical or functional characteristics, solely to support (1) the launch or return of a launch vehicle, spacecraft (including Space Station), or payload; or (2) the operations or use in space of a launch vehicle, spacecraft (including Space Station), or payload.

(c) The article's potential use is solely to support (1) the launch or return of a launch vehicle, spacecraft (including Space Station), or payload; or (2) the operations or use in space of a launch vehicle, spacecraft (including Space Station), or payload.

(d) The article is available only from a source outside of the United States.

(e) The article is a component of a system purchased outside of the United States.

(f) The article is to be exported from the United States upon completion of its use as support equipment.

#### § 1217.106 Articles returned from space by NASA.

Pursuant to section 116 of Public Law 97-446, and HTSUS chapter VIII, page 98-25, the return of articles from space by NASA shall not be considered an importation, and an entry of such materials through U.S. Customs shall not be required. This provision is applicable to articles returned from space whether or not the articles were launched into space aboard a NASA vehicle.

Dated: September 10, 1991.

Richard H. Truly,  
Administrator.

[FR Doc. 91-22281 Filed 9-17-91; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 878

[Docket No. 87P-0161]

#### Medical Devices; Reclassification and Codification of Absorbable Poly(Glycolide/L-Lactide) Surgical Suture

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the reclassification and codification of the absorbable poly(glycolide/L-lactide) surgical suture (PGL suture). FDA issued an order in the form of a letter to the manufacturer reclassifying the PGL suture from class III into class II.

**EFFECTIVE DATES:** The reclassification was effective October 4, 1989. This final rule becomes effective October 18, 1991.

**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 May 4, 1987, FDA filed the reclassification petition submitted by Advanced Bioresearch Associates, Danville, CA 94526-4617, on behalf of United States Surgical Corp. (U.S. Surgical), Norwalk, CT 06856, requesting reclassification of the PGL suture from class III into class II.

FDA bases its decision to reclassify PGL sutures, in part, on the recommendation of the General and Plastic Surgery Devices Panel (the Panel). The Panel, during an open public meeting on August 28, 1987, recommended that FDA reclassify the PGL suture from class III into class II and that FDA assign a low priority to the development of a performance standard for the generic type of device under section 514 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d).

FDA fully considered the Panel's recommendation, and reviewed various statements offered by persons who oppose U.S. Surgical's petition for reclassification of the PGL suture. After reviewing all data in the petition and presented before the Panel, and after considering the Panel's recommendation, FDA ordered the reclassification of the PGL suture from class III into class II. On September 14, 1989, FDA sent to the petitioner an

order, by letter, which reclassified the PGL suture, and substantially equivalent devices of this generic type, from class III into class II, to be effective on October 4, 1989, with a low priority for the development of a performance standard.

On November 2, 1989, Ethicon, Inc., submitted a petition for reconsideration. FDA conducted a thorough and careful review of all arguments, particularly those alleging that the record evidence was inadequate to support the reclassification of the PGL suture. Additionally, U.S. Surgical's comments on Ethicon's reconsideration petition and Ethicon's response to U.S. Surgical's comments were considered. On July 5, 1990, FDA issued an order denying the petition for reconsideration.

FDA has completed its review of the petition for reconsideration and concluded that the generic type of device, the PGL suture, and all devices substantially equivalent to this generic type were appropriately reclassified from class III into class II with a low priority for the development of a performance standard.

As required by 21 CFR 860.136(b)(6), FDA is announcing the reclassification of the generic type of device from class III into class II.

#### 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:** 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. New § 878.4493 is added to subpart E to read as follows:

**§ 878.4493 Absorbable poly(glycolide/L-lactide) surgical suture.**

(a) *Identification.* An absorbable poly(glycolide/L-lactide) surgical suture (PGL suture) is an absorbable sterile,

flexible strand as prepared and synthesized from homopolymers of glycolide and copolymers made from 90 percent glycolide and 10 percent L-lactide, and is indicated for use in soft tissue approximation. A PGL suture meets United States Pharmacopeia (U.S.P.) requirements as described in the U.S.P. "Monograph for Absorbable Surgical Sutures;" it may be monofilament or multifilament (braided) in form; it may be uncoated or coated; and it may be undyed or dyed with an FDA-approved color additive. Also, the suture may be provided with or without a standard needle attached.

(b) *Classification.* Class II.

Dated: August 13, 1991.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 91-22502 Filed 9-17-91; 8:45 am]

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## DEPARTMENT OF DEFENSE

### Department of the Navy

#### 32 CFR Part 706

#### Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972; Amendment

**AGENCY:** Department of the Navy, DOD.

**ACTION:** Final rule.

**SUMMARY:** The Department of the Navy is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), to reflect that the Judge Advocate General of the Navy has determined that USS ANZIO (CG 68) is a vessel of the Navy which, due to its special construction and purpose, cannot comply fully with certain provisions of the 72 COLREGS without interfering with its special functions as a naval cruiser. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

**EFFECTIVE DATE:** September 4, 1991.

**FOR FURTHER INFORMATION CONTACT:** Captain R.R. Rossi, JAGC, U.S. Navy, Admiralty Counsel, Office of the Judge

Advocate General, Navy Department, 200 Stovall Street, Alexandria, VA 22332-2400, Telephone number: (703) 325-9744.

**SUPPLEMENTARY INFORMATION:** Pursuant to the authority granted in 33 U.S.C. 1605, the Department of the Navy amends 32 CFR part 706. This amendment provides notice that the Judge Advocate General of the Navy, under authority delegated by the Secretary of the Navy, has certified that USS ANZIO (CG 68) is a vessel of the Navy which, due to its special construction and purpose, cannot comply fully with 72 COLREGS, Annex I, section 3(a), pertaining to the location of the forward masthead light in the forward quarter of the ship, the placement of the after masthead light, and the horizontal distance between the forward and after masthead lights, without interfering with its special functions as a naval cruiser. The Judge Advocate General of the Navy has also certified that the aforementioned lights are located in closest possible compliance with the applicable 72 COLREGS requirements.

Moreover, it has been determined, in accordance with 32 CFR parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and contrary to public interest since it is based on technical findings that the placement of lights on this vessel in a manner differently from that prescribed herein will adversely affect the vessel's ability to perform its military functions.

#### List of Subjects in 32 CFR Part 706

Marine safety, Navigation (water), and Vessels.

#### PART 706—[AMENDED]

Accordingly, 32 CFR part 706 is amended as follows:

1. The authority citation for 32 CFR part 706 continues to read:

**Authority:** 33 U.S.C. 1605.

#### § 706.2 [Amended]

2. Table Five of § 706.2 amended by adding to the end of the table the following vessel:

Vessel	Number	Masthead lights not over all other lights and obstructions. Annex I, sec. 2(f)	Forward masthead light not in forward quarter of ship. Annex I, sec. 3(a)	After masthead light less than 1/2 ship's length aft of forward masthead light. Annex I, sec. 3(a)	Percentage horizontal separation attained
USS ANZIO.....	CG 68		X	X	36

Dated: September 4, 1991.

Approved:

J.E. Gordon,

Rear Admiral, JAGC, U.S. Navy Judge Advocate General.

[FR Doc. 91-22414 Filed 9-17-91; 8:45 am]

BILLING CODE 3310-01-M

### 32 CFR Part 706

#### Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972; Amendment

AGENCY: Department of the Navy, DOD.

ACTION: Final rule.

**SUMMARY:** The Department of the Navy is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), to reflect that the Judge Advocate General of the Navy has determined that USS PATRIOT (MCM 7) is a vessel of the Navy which, due to its special construction and purpose, cannot comply fully with certain provisions of the 72 COLREGS without interfering with its special functions as a mine countermeasures

ship. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

**EFFECTIVE DATE:** September 4, 1991.

**FOR FURTHER INFORMATION CONTACT:** Captain R.R. Rossi, JAGC, U.S. Navy, Admiralty Counsel, Office of the Judge Advocate General, Navy Department, 200 Stovall Street, Alexandria, VA 22332-2400, Telephone number: (703) 325-9744.

**SUPPLEMENTARY INFORMATION:** Pursuant to the authority granted in 33 U.S.C. 1605, the Department of the Navy amends 32 CFR part 706. This amendment provides notice that the Judge Advocate General of the Navy, under authority delegated by the Secretary of the Navy, has certified that USS PATRIOT (MCM-7) is a naval vessel which, due to its special construction and purpose, cannot comply fully with 72 COLREGS, Annex 1, section 3(a), pertaining to the placement of the after masthead light and the horizontal distance between the forward and after masthead lights, without interfering with its special functions as a Naval vessel. The Judge Advocate General of the Navy has also certified that the aforementioned lights

are located in closest possible compliance with the applicable 72 COLREGS requirements.

Moreover, it has been determined, in accordance with 32 CFR Parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and contrary to public interest since it is based on technical findings that the placement of lights on this ship in a manner differently from that prescribed herein, will adversely affect the vessel's ability to perform its military functions.

#### List of Subjects in 32 CFR Part 706

Marine safety, Navigation (water), and Vessels.

#### PART 706—[AMENDED]

Accordingly, 32 CFR part 706 is amended as follows:

1. The authority citation for 32 CFR part 706 continues to read:

Authority: 33 U.S.C. 1605.

#### § 706.2 [Amended]

2. Table Five of § 706.2 is amended by adding to the end of the table the following vessel:

Vessel	Number	Masthead lights not over all other lights and obstructions. Annex I, sec. 2(f)	Forward masthead light not in forward quarter of ship. Annex I, sec. 3(a)	After masthead light less than 1/2 ship's length aft of forward masthead light. Annex I, sec. 3(a)	Percentage horizontal separation attained
USS PATRIOT.....	MCM 7			X	64