to the management, prophylaxis, or treatment of anginal attacks. The proposal was based on a lack of substantial evidence of effectiveness as required by section 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)) and 21 CFR 314.126.

Neither the holder of the conditionally approved ANDA's nor any other person filed a written notice of appearance and request for hearing as provided by the notice (63 FR 34188). The failure to file such an appearance and request for hearing constitutes a waiver of the opportunity for hearing. Accordingly, approval of the following conditionally approved ANDA's is being withdrawn:

1. ANDA 86–194; Cardilate Chewable Tablets containing 10 milligrams (mg) erythrityl tetranitrate per tablet; Glaxo Wellcome (formerly Burroughs Wellcome), 3030 Cornwallis Rd., P.O. Box 12700, Research Triangle Park, NC 27709–2700.

2. ANDA 86–203; Cardilate Tablets containing 5, 10, or 15 mg of erythrityl tetranitrate per tablet; Glaxo Wellcome.

Although FDA withdrew approval of ANDA 86–194 in the **Federal Register** of February 13, 1996 (61 FR 5563), based on the applicant's written request, this notice constitutes FDA's final conclusions on the effectiveness of the product.

Any drug product that is identical, related, or similar to the drug products named previously and is not the subject of an approved new drug application is covered by the applications listed previously and is subject to this notice (21 CFR 310.6). Any person who wishes to determine whether a specific product is covered by this notice should write to the Division of Prescription Drug Compliance and Surveillance (address above).

The Director of the Center for Drug Evaluation and Research, under section 505 of the act and under authority delegated to her (21 CFR 5.82), finds that, on the basis of new information on the drugs and the evidence available when the applications were approved, there is a lack of substantial evidence that the products named previously will have the effects they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in their labeling.

Therefore, based on the foregoing finding, approval of ANDA's 86–194 and 86–203 and all their amendments and supplements are withdrawn effective November 16, 1998. Shipment in interstate commerce of these products or of any identical, related, or similar product that is not the subject of a fully approved new drug application will then be unlawful.

Dated: September 25, 1998.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 98–27739 Filed 10–15–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0530]

FDA Modernization Act of 1997: Modifications to the List of Recognized Standards; Availability; Withdrawal of Draft Guidance ''Use of IEC 60601 Standards; Medical Electrical Equipment''

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the publication of the modifications to the list of standards that will be recognized for use in the premarket review process and withdrawing its draft guidance entitled ''Use of IEC 60601 Standards; Medical Electrical Equipment.'' This will assist manufacturers who elect to declare conformity with consensus standards to meet all or part of medical device review requirements.

DATES: This recognition of standards is effective on November 16, 1998; however, written comments concerning this notice may be submitted at any time.

ADDRESSES: Submit written requests for single copies of ''Modifications to the List of Recognized Standards'' to the Division of Small Manufacturers Assistance (DSMA), Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301–443–8818. Written comments concerning this document must be submitted to the contact person listed below. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance. This document may also be accessed via the Internet at FDA's web site ''http://www.fda.gov/cdrh''.

FOR FURTHER INFORMATION CONTACT: To comment on this document and/or to recommend additional standards for recognition: James J. McCue, Jr., Center for Devices and Radiological Health (HFZ–101), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–4766, ext. 137.

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115, 111 Stat. 2296 (1997)) amends section 514 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360d), allowing the agency to recognize consensus standards established by international and national standards development organizations that may be used to satisfy identified portions of device premarket review submissions or other requirements. In a previous notice published in the **Federal Register** of February 25, 1998 (63 FR 9561), FDA announced the availability of a guidance document entitled ''Recognition and Use of Consensus Standards,'' which describes how FDA will implement that part of FDAMA, and provided the initial list of recognized standards (the February 1998 notice). This document announces modifications to the list of consensus standards to be recognized for use by FDA.

II. Recognition and Use of IEC 60601 Standards

In the **Federal Register** of January 13, 1998 (63 FR 1974), FDA published a notice that announced the availability of a draft guidance entitled ''Use of IEC 60601 Standards; Medical Electrical Equipment'' (the January 1998 notice). The purpose of the draft was to provide guidance to the Office of Device Evaluation reviewers on the use of the International Electrotechnical Commission (IEC) 60601 series of standards, including declarations of conformity to the standards, during the evaluation of premarket submissions for electrical medical devices.

FDA has decided not to finalize this draft guidance document. Instead, recognition of the IEC 60601 standards will occur by listing in this publication ''Modifications to the List of Recognized Standards.'' There appears to be little, if any, benefit to finalizing guidance on FDA's use of IEC 60601 standards in a separate document from the general recognition of consensus standards under FDAMA, announced in the February 1998 notice, especially as there is a fair amount of overlap between the two documents.

In response to the January 1998 notice, FDA received one comment on the draft guidance. The comment contained some specific recommendations concerning IEC 60601–1–2 on Electromagnetic Compatibility (EMC). These recommendations were considered in developing the supplementary information sheet for this standard that is maintained on the FDA Web site. The comment also included recommended changes to the draft guidance which are now not necessary because the draft guidance will not be finalized. However, most of the recommended changes were accommodated in the guidance ''Recognition and Use of Consensus Standards'' announced in the February 1998 notice. Finally, the comment recommended an additional standard (newly published) in the 60601 series for recognition. This standard will be treated as an official recommendation according to the ''Guidance on the Recognition and Use of Consensus Standards'' and will be considered in due course.

In the February 1998 notice, one of the recognized standards was IEC 60601–1. This ''Modifications to the List of Recognized Standards'' includes the IEC 60601–1 standard again because the associated supplementary information sheet has been modified, partly to include reference to the two amendments to IEC 60601–1 which are being recognized by this modified list. Also, some of the IEC 60601 part 2 standards referenced in the January 1998 notice do not appear in this modified list. This is because there was not sufficient time to complete the detailed evaluations and prepare the supplementary information sheets for these standards. They should appear in future **Federal Register** notices of recognized standards.

III. List of Recognized Standards

Modifications to the list of consensus standards to be recognized for use in premarket review and to meet other requirements are presented at the end of this document. This list is also maintained on the FDA Web site ''http://www.fda.gov/cdrh''. Also posted on the Web site are supplementary information sheets for each recognized standard. These information sheets list the address(es) where the standard can be obtained, information on any limitations on the application of the standard in medical device review or in satisfying other regulatory requirements, and a list of devices for which declarations of conformity with the recognized standard will be routinely accepted by agency reviewers. In addition to these documents, the web site contains answers to frequently asked questions regarding the use of recognized standards.

In the February 1998 notice, one of the recognized standards, under the OB–GYN/GASTROENTEROLOGY heading, was ASTM D3492–96. This publication ''Modifications to the List of Recognized Standards'' removes the February 25, 1998, recognition and adds recognition of ASTM 3492–96 in part. The associated supplementary information sheet excludes from recognition the standards quality inspection for air burst properties and water leakage which are different than the FDA requirements.

IV. Recommendation of Standards for Recognition by FDA

Modifications to the list of recognized consensus standards related to medical devices will be announced in the **Federal Register** at least once a year, or more often if necessary.

Any person may recommend consensus standards as candidates for recognition under the new paragraph of section 514 of the act by submitting such recommendations, with justification, to DSMA (address above). To be properly considered, such recommendations should contain, at a minimum, the following information: (1) Title of standard, (2) any reference number and date, (3) name and address of the nationally or internationally recognized standards development organization, (4) a proposed list of devices for which a declaration of conformity should routinely apply, and (5) a brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.

V. Electronic Access

In order to receive the guidance document ''Recognition and Use of Consensus Standards,'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at the second voice prompt press 2, and then enter the document number 321, followed by the pound sign (#). Then follow the remaining voice prompts to complete your request. Persons interested in obtaining a copy of the guidance may also do so by using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a regular basis, the CDRH home page includes the guidance document ''Guidance on the Recognition and Use of Consensus Standards,'' as well as the list of recognized standards and details on their application, and information on obtaining copies. The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''.

A text-only version of the CDRH Web site is also available from a computer or VT–100 compatible terminal by dialing 800-222-0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there, follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA Home Page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there, select Center for Devices and Radiological Health for general information or arrow down for specific topics.

VI. Comments

Interested persons may, at any time, submit to the contact person listed above written comments regarding this notice. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments will be considered in determining whether to amend the current guidance.

Dated: October 8, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

BILLING CODE 4160–01–F

The text of the list is set forth below:

	Title of Standard	Reference No. and Date
	Generally Applicable Standards	
4.....	Medical Electrical Equipment - Part 1: General Requirements for Safety, Amendment 1, 1991-11 Amendment 2, 1995-03	IEC 60601-1 (1988)
5.....	Medical Electrical Equipment - Part 1: General Requirements for Safety; Safety Requirements for Medical Electrical Systems, Amendment 1(1995-11)	IEC 60601-1-1 (1992-06)
6.....	Medical Electrical Equipment - Part 1: General Requirements for Safety; Electromagnetic Compatibility - Requirements and Tests	IEC 60601-1-2 (First Edition, 1993-04)
7.....	Medical Electrical Equipment - Part 1: General Requirements for Safety; General Requirements for Radiation Protection in Diagnostic X-Ray Equipment	IEC 60601-1-3 (1994-07)
8.....	Medical Electrical Equipment - Part 1: General Requirements for Safety; 4. Collateral Standard: Programmable Electrical Medical Systems	IEC 60601-1-4:1996
9.....	Medical Devices - Risk Analysis	EN 1441:1997
	Anesthesia	
1.....	Standard Specification for Minimum Performance and Safety Requirements for Resuscitators Intended for Use with Humans	ASTM F 920-93
2.....	Standard Specification for Ventilators Intended for Use in Critical Care	ASTM F 1100-90
3.....	Standard Specification for Minimum Performance And Safety Requirements for Components and Systems of Anesthesia Gas Machines	ASTM F 1161-88
4.....	Standard Specification for Cuffed and Uncuffed Tracheal Tubes	ASTM F 1242-96
5.....	Standard Specification for Alarm Signals in Medical Equipment Used in Anesthesia and Respiratory Care	ASTM F1463-93
6.....	Standard Specification for Oxygen Concentrators for Domiciliary Use	ASTM F1464-93
7.....	Standard Specification for Pediatric Tracheostomy Tubes	ASTM F1627-95
8.....	Safety Standard for Pressure Vessels for Human Occupancy	ASME PVHO-1-1997
9.....	Medical Electrical Equipment Part 2: Particular Requirements for the Safety of Lung Ventilators for Medical Use	IEC 60601-2-12:1988-12
10.....	Medical Electrical Equipment Part 2: Particular Requirements for the Safety of Anesthetic Machines	IEC 60601-2-13:1998-05

11.....	Medical Electrical Equipment Part 3-1: Essential Performance Requirements for Transcutaneous Oxygen and Carbon Dioxide Partial Pressure Monitoring Equipment	IEC 60601-3-1:1996-08
12.....	Tracheal Tubes-Part 1: General Requirements	ISO 5361-1:1988
13.....	Tracheal Tubes-Part 2: Oro-tracheal and Naso-tracheal Tubes of Magill Type (plain and cuffed)	ISO 5361-2:1993
14.....	Tracheal Tubes-Part 3: Murphy Type	ISO 5361-3:1984
15.....	Tracheal Tubes-Part 4: Cole Type	ISO 5361-4:1987
16.....	Tracheal Tubes-Part 5: Requirements and Methods of Test for Cuffs and Tubes	ISO 5361-5:1984
17.....	Tracheostomy Tubes-Part 3: Pediatric Tracheostomy Tubes	ISO 5366-3:1994
18.....	Oxygen Concentrators for Medical Use	ISO 8359:1996
19.....	Resuscitators Intended for Use with Humans	ISO 8382:1988
20.....	Anesthesia and Respiratory Care Alarm Signals, Part 1: Visual Alarm Signals	ISO 9703-1:1992
21.....	Anesthesia and Respiratory Care Alarm Signals, Part 2: Auditory Alarm Signals	ISO 9703-2:1994
22.....	Standard for Health Care Facilities Chapter 19 - Hyperbaric Facilities	NFPA 99-1996

Biocompatibility		
1.....	Standard Guide for Performance of the Chinese Hamster Ovary Cell/Hypoxanthine Guanine Phosphoribosyl Transferase Gene Mutation Assay	ASTM E 1262-88 (r1996)
2.....	Standard Guide for Conduct of Micronucleus Assays in Mammalian Bone Marrow Erythrocytes	ASTM E 1263-97
3.....	Standard Guide for Performing the Mouse Lymphoma Assay for Mammalian Cell Mutagenicity	ASTM E 1280-97
4.....	Standard Test Method for Conducting a 90-Day Oral Toxicity Study in Rats	ASTM E 1372-90
5.....	Standard Practice for the in vitro Rat Hepatocyte DNA Repair Assay	ASTM E 1397-91
6.....	Standard Practice for the in vivo Rat Hepatocyte DNA Repair Assay	ASTM E 1398-91
7.....	Standard Practice for Testing Biomaterials in Rabbits for Primary Skin Irritation	ASTM F 719-81 (r1996)
8.....	Standard Practice for Testing Guinea Pigs for Contact Allergens: Guinea Pig Maximization Test	ASTM F 720-81 (r1996)
9.....	Standard Practice for Evaluating Material Extracts by Intracutaneous Injection in the Rabbit	ASTM F 749-87 (r1996)
10.....	Standard Practice for Evaluating Material Extracts by Systemic Injection in the Mouse	ASTM F 750
11.....	Standard Practice for Short Term Screening for Implant Material	ASTM F 763-87
12.....	Standard Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices	ASTM F 813-83 (r1996)
13.....	Standard Test Method for Agar Diffusion Cell Culture Screening for Cytotoxicity	ASTM F 895-84 (r1995)

14.....	Standard Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone	ASTM F 981-93
15.....	Standard Practice for Subcutaneous Screening Test for Implant Materials	ASTM F 1408-92
16.....	Standard Guide for Performance of Lifetime Bioassay for the Tumorigenic Potential of Implant Materials	ASTM F 1439-92(r1996)
17.....	Biological Evaluation for Medical Devices-Part 5: Tests for Cytotoxicity: in vitro Methods	ANSI/AAMI/ISO 10993-5 (1993)
18.....	Biological Evaluation of Medical Devices-Part 6: Test for Local Effects After Implantation	ANSI/AAMI/ISO 10993-6 (1995)
19.....	Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Sensitization	ANSI/AAMI/ISO 10993-10 (1995)
20.....	Biological Evaluation of Medical Devices-Part 10: Maximization Sensitization Test	ANSI/AAMI/ISO 10993-10 (1995)
21.....	Biological Evaluation of Medical Devices-Part 11: Tests for Systemic Toxicity	ISO 10993-11 (1993)
22.....	Biological Evaluation of Medical Devices-Part 12: Sample Preparation and Reference Materials	ANSI/AAMI/ISO 10993-12 (1996)
23.....	Biological Reactivity Tests, In Vitro-Direct Contact Test <87>	USP 23
24.....	Biological Reactivity Tests, In Vitro-Elution Test <87>	USP 23
25.....	Biological Reactivity Tests, In Vivo, Classification of Plastics - Intracutaneous Test <88>	USP 23
26.....	Biological Reactivity Tests, In Vivo, Classification of Plastics, Sample Preparation <88>	USP 23
27.....	Biological Reactivity Tests, In Vivo - Systemic Injection Test <88>	USP 23

Cardiovascular/Neurology

1.....	Disposable ECG Electrodes	AAMI EC12-1991
2.....	ECG Cables and Leadwires	AAMI EC53-1995
3.....	Intracranial Pressure Monitoring Devices	AAMI NS28
4.....	Electronic or Automated Sphygmomanometers	AAMI SP10-1992
5.....	Cardiovascular Implants - Vascular Prostheses (rev. of ANSI/AAMI VP20-1986)	AAMI VP 20-1994
6.....	Standard Specification for Cast Cobalt-Chromium-Molybdenum Alloy for Surgical Implant Applications	ASTM F 75-92
7.....	Standard Specification for Wrought Cobalt-20 Chromium-15 Tungsten-10 Nickel Alloy for Surgical Implant Applications	ASTM F 90-96
8.....	Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium Alloy for Surgical Implant Applications	ASTM F 136-96
9.....	Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants	ASTM F 138-97
10.....	Standard Specification for Unalloyed Tantalum for Surgical Implant Applications	ASTM F 560-92

11.....	Standard Specification for Wrought Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy for Surgical Implant Applications	ASTM F 562-95
12.....	Standard Specification for Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy Forgings for Surgical Implant Applications [UNS R30035]	ASTM F 961-96
13.....	Standard Specification for Wrought Cobalt-Chromium-Nickel-Molybdenum-Iron Alloy for Surgical Applications	ASTM F 1058-91
14.....	Recommended Practice for Selection of Blood for In Vitro Hemolytic Evaluation of Blood Pumps	ASTM F 1830
15.....	Recommended Practice for Assessment of Hemolysis in Continuous Flow Blood Pumps	ASTM F 1841
16.....	Medical Electrical Equipment-Part 2: Particular Requirements for the Safety of Nerve and Muscle Stimulators	IEC 60601-2-10 (1987)
17.....	Medical Electrical Equipment, Part 2: Particular Requirements for the Safety of Electrocardiographs	IEC 60601-2-25 (1993)
18.....	Medical Electrical Equipment, Part 2: Particular Requirements for the Safety of Electrocardiographic Monitoring Equipment	IEC 60601-2-27 (1994)
19.....	Medical Electrical Equipment, Part 2: Particular Requirements for the Safety of Automatic Cycling Indirect Blood Pressure Monitoring Equipment	IEC 60601-2-30 (1995)
20.....	Medical Electrical Equipment, Part 2: Particular Requirements for the Safety of External Cardiac Pacemakers with Internal Power Source	IEC 60601-2-31 (1994)

	Dental/ENT	
1.....	Standard Specifications for Unalloyed Titanium for Surgical Implant Applications	ASTM F67-95
2.....	Standard Specification for Cast Cobalt-Chromium-Molybdenum Alloy for Surgical Implant Applications	ASTM F75-92
3.....	Standard Specification for Wrought Cobalt-20 Chromium-15 Tungsten-10 Nickel Alloy for Surgical Implant Applications (UNS R30605)	ASTM F90-96
4.....	Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy (R56401) for Surgical Implant Applications	ASTM F136-96
5.....	Standard Specification for Stainless Steel Bar and Wire for Surgical Implants (Special Quality)	ASTM F138-92
6.....	Standard Specification for Wrought-18 Chromium-14 Nickel-2.5 Molybdenum Stainless Sheet and Strip for Surgical Implants (UNS S31673)	ASTM F139-96

7.....	Standard Specification for Wrought Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy for Surgical Implant Applications	ASTM F562-95
8.....	Standard Specification for Titanium-6 Aluminum-4 Vanadium ELI Alloy Forgings for Surgical Implants (UNS R56401)	ASTM F620-96
9.....	Standard Specification for Stainless Steel Forgings for Surgical Implants	ASTM F621-92
10.....	Standard Specification for Wrought Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy Plate, Sheet, and Foil for Surgical Implants	ASTM F688-95
11.....	Standard Specification for 18 Chromium-12.5 Nickel-2.5 Molybdenum Stainless Steel for Cast and Solution-Annealed Surgical Implant Applications	ASTM F745-95
12.....	Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants (UNS R31537)	ASTM F799-96
13.....	Standard Specification for Cobalt-Nickel-Chromium-Molybdenum Alloy Forgings for Surgical Implant Applications	ASTM F961-96
14.....	Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation	ASTM F1088-87 (R1992)
15.....	Standard Specification for Wrought Cobalt-20 Chromium-15 Tungsten-20 Nickel Alloy Surgical Fixation Wire (UNS R30605)	ASTM F1091-91 (R1996)
16.....	Standard Specification for Titanium-6 Aluminum-4 Vanadium Alloy Castings for Surgical Implants (UNS R56406)	ASTM F1108-97
17.....	Standard Specification for Composition of Ceramic Hydroxylapatite for Surgical Implants	ASTM F1185-88 (R1993)
18.....	Standard Specification for Wrought Titanium-6 Aluminum-7 Niobium Alloy for Surgical Implant Applications	ASTM F1295-97
19.....	Standard Specification for Wrought Nitrogen Strengthened-22 Chromium-12.5 Nickel-5 Manganese-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants	ASTM F1314-95
20.....	Standard Specification for Unalloyed Titanium Wire for Surgical Implant Applications	ASTM F1341-92
21.....	Standard Specification for Wrought-18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Surgical Fixation Wire (UNS S31673)	ASTM F1350-96
22.....	Standard Specification for Cobalt-Chromium-Molybdenum Powder for Coating of Orthopaedic Implants	ASTM F1377-92
23.....	Standard Specification for Wrought TI-6AI-4V Alloy for Surgical Implant Applications	ASTM F1472-93
24.....	Standard Specification for Wrought Cobalt-28 Chromium-6-Molybdenum Alloy for Surgical Implants	ASTM F1537-94
25.....	Standard Specification for Titanium and Titanium-6% Aluminum-4% Vanadium Alloy Powders for Coatings of Surgical Implants	ASTM F1580-95

26.....	Standard Specification for Wrought Nitrogen Strengthened-21 Chromium-10 Nickel-3 Manganese-2.5 Molybdenum Stainless Steel Bar for Surgical Implants	ASTM F1586-95
27.....	Standard Specification for Calcium Phosphate Coatings for Implantable Materials	ASTM F1609-95
28.....	Standard Specification for Wrought Titanium-13 Niobium-13 Zirconium Alloy for Surgical Implant Applications	ASTM F1713-96
29.....	Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of Endoscopic Equipment	IEC 60601-2-18(1996)
30.....	Implants for Surgery - Metallic Materials - Part 1: Wrought Stainless Steel	ISO 5832-1:1997
31.....	Implants for Surgery - Metallic Materials - Part 2: Unalloyed Titanium	ISO 5832-2:1993
32.....	Implants for Surgery - Metallic Materials - Part 3: Wrought Titanium 6-Aluminum 4-Vanadium Alloy	ISO 5832-3:1996
33.....	Implants for Surgery - Metallic Materials - Part 4: Cobalt-Chromium-Molybdenum Casting Alloy	ISO 5832-4:1996
34.....	Implants for Surgery - Metallic Materials - Part 5: Wrought Cobalt-Chromium-Tungsten-Nickel Alloy	ISO 5832-5:1993
35.....	Implants for Surgery - Metallic Materials - Part 6: Wrought Cobalt-Nickel-Chromium-Molybdenum Alloy	ISO 5832-6:1997
36.....	Implants for Surgery - Metallic Materials - Part 9: Wrought High Nitrogen Stainless Steel First Edition	ISO 5832-9:1992
37.....	Implants for Surgery - Metallic Materials - Part 10: Wrought Titanium 5-Aluminum 2.5-Iron	ISO 5832-10:1996
38.....	Implants for Surgery - Metallic Materials - Part 11: Wrought Titanium 6-Aluminum 7-Niobium Alloy	ISO 5832-11:1994
39.....	Implants for Surgery - Metallic Materials - Part 12: Wrought Cobalt-Chromium-Molybdenum Alloy	ISO 5832-12:1996

General Plastic Surgery/General Hospital

1.....	For Blood Transfusion Micro-Filter	AAMI BF7-1989 (revising BF7-1982)
2.....	Standard Specification for Electronic Thermometers for Intermittent Determinations of Patient Temperature	ASTM E1112-86 (r1991)
3.....	Standard Specification for Implantable Polytetrafluoroethlene (PTFE) Polymer Fabricated in Sheet, Tube, and Rod Shapes	ASTM F754-88
4.....	Standard Specification for Elastomer Facial Implants	ASTM F881-94
5.....	Standard Performance and Safety Specification for Cryosurgical Medical Instrumentation	ASTM F882-96a
6.....	Standard Specification for Soft Tissue Expanders	ASTM F1441-92
7.....	Medical Electrical Equipment - Part 2: Particular Requirements for Safety of Baby Incubators, Amend. No. 1	IEC 60601-2-19 (1990-12) (r1996-10)

8.....	Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of Transport Incubators, Amend. No. 1 (1996-10)	IEC 60601-2-20 (1990-12)
9.....	Medical Electrical Equipment - Part 2: Particular Requirements for Safety of Infant Radiant Warmers, Amend. No. 1 (1996-10)	IEC 60601-2-21(1994-02)
10.....	Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of Electrically Operated Hospital Beds	IEC 60601-2-38(1996)
11.....	Conical Fittings with a 6% (luer) Taper for Syringes, Needles and Certain Other Medical Equipment - Part 1: General Requirements	ISO 594/1 (First edition 1986-06-15)
12.....	Conical Fittings with a 6% (luer) Taper for Syringes, Needles and Certain Other Medical Equipment - Part 2: Lock Fittings	ISO 594/2 (first edition 1991-05-01)
13.....	Reusable All-glass or Metal-and-glass Syringes for Medical Use - Part 1: Dimensions	ISO 595/1 (first edition 1986-12-15)
14.....	Reusable-glass or Metal-and-glass Syringes for Medical Use - Part 2: Design, Performance Requirements and Tests	ISO 595/2 (first edition 1987-12-15)
15.....	Sterile Hypodermic Needles for Single Use	ISO 7864:1993
16.....	Sterile Hypodermic Syringes for Single Use - Part 1: Syringes for Manual Use	ISO 7886-1:1993
17.....	Infusion Equipment for Medical Use - Part 4: Infusion Sets for Single Use	ISO 8536-4 (first edition 1987-11-01)
18.....	Sterile Single-Use Syringes, with or without Needle, for Insulin	ISO 8537:1991
19.....	Transfusion Equipment for Medical Use - Part 4: Transfusion Sets for Single Use	ISO 1135-4 (first edition 1987-12-01)
20.....	Sterile - Single-Use Intravascular Catheters Part 1: General Requirements	ISO 10555-1
21.....	Sterile Single-Use Intravascular Catheter Part 3: Central Venous Catheter	ISO 10555-3
22.....	Absorbable Surgical Sutures	USP 21
23.....	Nonabsorbable Surgical Sutures	USP 21
24.....	Sutures - Diameter <861>	USP 21
25.....	Sutures Needle Attachment <871>	USP 21
26.....	Tensile Strength <881>	USP 21
27.....	Sterile Sodium Chloride for Irrigation	USP 23 <11>
28.....	Sterile Water for Injection	USP 23 <11>

	In Vitro Devices	
12.....	Definitions of Quantities and Conventions Related to Blood pH and Gas Analysis; Approved Standard	NCCLS C12-A (1994)
13.....	Performance Characteristics for Devices Measuring P02 and PC02 in Blood Samples; Approved Standard	NCCLS C21-A (1992)
14.....	Internal Quality Control Testing; Principles and Definitions; Approved Guideline	NCCLS C24-A (1991)

15.....	Fractional Oxyhemoglobin, Oxygen Content and Saturation, and Related Quantities in Blood: Terminology, Measurement, and Reporting; Approved Guideline	NCCLS C25-A (1997)
16.....	Blood Gas Preanalytical Considerations: Specimen Collection, Calibration, and Controls; Approved Guideline	NCCLS C27-A (1993)
17.....	Standardization of Sodium and Potassium Ion-selective Electrode Systems to the Flame Photometric Reference Method; Approved Standard	NCCLS C29-A (1995)
18.....	Ancillary (Bedside) Blood Glucose Testing	NCCLS C30-A
19.....	Ionized Calcium Determinations: Precollection Variables, Specimen Choice, Collection, and Handling; Approved Guideline	NCCLS C31-A (1995)
20.....	Sweat Testing; Sample Collection and Quantitative Analysis; Approved Guideline	NCCLS C34-A (1994)
21.....	Erythrocyte Protoporphyrin Testing; Approved Guideline	NCCLS C42-A (1996)
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