economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this reclassification action is consistent with the regulatory 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 by lowering their costs. The agency therefore certifies that this reclassification action, if finalized, 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.

XIV. Request for Comments

Interested persons may, on or before October 28, 1999, submit to the Dockets Management Branch (address above) written comments regarding this document. 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 may be seen in the office above between 9 a.m. and 4 p.m. Monday through Friday.

Dated: June 30, 1999.

Linda S. Kahan,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–2098]

Computer-Controlled Potentially High Risk Medical Devices—List of Device Types

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Computer-Controlled Potentially High Risk Medical Devices—List of Device Types.'' FDA has developed a list of types of computer-controlled, potentially high-risk medical devices that have the potential for the most serious consequences for the patient should they fail because of date-related problems. This list will be useful to FDA, manufacturers, and health care facilities as they prioritize and assess their efforts to prevent potential Year 2000 (Y2K) problems with medical devices. This list has previously been made available on FDA's web site.

FOR FURTHER INFORMATION CONTACT: Thomas B. Shope, Center for Devices and Radiological Health (HFZ–140), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–3314, ext. 32.

SUPPLEMENTARY INFORMATION:

I. Background

In order to more sharply focus agency efforts related to the possible impact of the Y2K date problem on medical devices, FDA has developed a list of types of computer-controlled, potentially high-risk medical devices that have the potential for the most serious consequences for the patient should they fail. Inclusion of a type of device on this list does not mean that all devices of this type have a date-related problem (are Y2K noncompliant) or, if they are Y2K noncompliant, that they necessarily pose a significant risk to patients. Rather, this list includes those types of devices that could pose a risk to patients if the date-related failure affects the function or operation of the device. FDA will use this list to identify those devices (and manufacturers) that would present the most serious risks to patients if they experienced a Y2K related failure. This will help the agency to focus attention on the devices that could present the highest levels of risk.

The list includes the types of computer-controlled devices whose failure to function as designed or expected could result in immediate and serious adverse health consequences. These potentially high-risk devices are those that are:

1. Used in the direct treatment of a patient where device failure could compromise the treatment or could injure the patient, or
2. Used in the monitoring of vital patient parameters and whose data are immediately necessary for effective treatment, or
3. Necessary to support or sustain life during treatment or patient care.

The list does not include diagnostic devices whose failure would not result in immediate harm to the patient, even though the diagnostic information they provide might be unavailable or incorrect. However, a few diagnostic devices have been included, if the results of calculations or other information processing by the device would not be readily apparent to the user, and a Y2K failure of the device could reasonably lead to serious adverse health consequences before being detected by the user.

This list of computer-controlled potentially high-risk devices will be used by FDA for several purposes and can also provide a guide to health care facilities regarding the types of devices that should receive priority in their assessment and remediation of medical devices.

FDA will identify all manufacturers of these types of devices. These manufacturers will be candidates for further oversight to provide increased assurance that product Y2K status has been carefully assessed and that any Y2K-related upgrade has been developed and tested in accordance with the quality system regulations. That oversight may include facility inspection or audit. FDA will also ascertain whether these manufacturers have made Y2K status information available to users, and that, where appropriate, users have received notification regarding any remedial action that may be necessary.

This list should not be considered a definitive list of all high-risk devices. It was developed by FDA staff based on their assessment of the types of devices that have the greatest potential for direct patient risk should they fail to correctly process date-related information. FDA will update the list, if necessary.

II. Electronic Access

In order to receive a copy of ''Computer-Controlled Potentially High Risk Medical Devices—List of Device Types'' 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 second voice prompt press 2, and then enter the document number (1142) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the list may also do so 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 WWW. Updated on a regular basis, the CDRH home page includes ''Computer-Controlled Potentially High Risk Medical Devices—List of Device Types,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''. ''Computer-Controlled Potentially High Risk Medical Devices—List of Device Types'' will also be available at ''http://www.fda.gov/cdrh/yr2000/cdrh/phrds/phrds.html''.

III. List of Potentially High Risk Devices

The following list contains the potentially high-risk device types. Where the generic device type has been classified by FDA, the list includes the section number in Title 21 of the Code of Federal Regulations where the device type is described. For those devices cleared for market through the premarket approval application process or which have not yet been classified, no classification regulation number is given.

A. Classified Devices

(Classification regulation number followed by classification name)
862.1345 Glucose Test System
862.2140 Centrifugal Chemistry Analyzer for Clinical Use
862.2150 Continuous Flow Sequential Multiple Chemistry Analyzer for Clinical Use
862.2160 Discrete Photometric Chemistry Analyzer for Clinical Use
862.2170 Micro Chemistry Analyzer for Clinical Use
868.1150 Indwelling Blood Carbon Dioxide Partial Pressure (P_{C02}) Analyzer
868.1200 Indwelling Blood Oxygen Partial Pressure (P_{02}) Analyzer
868.1730 Oxygen Uptake Computer
868.2375 Breathing Frequency Monitor
868.2450 Lung Water Monitor
868.5160 Gas Machine for Anesthesia or Analgesia
868.5330 Breathing Gas Mixer
868.5400 Electroanesthesia Apparatus
868.5440 Portable Oxygen Generator
868.5470 Hyperbaric Chamber
868.5610 Membrane Lung (for Long-Term Pulmonary Support)
868.5830 Autotransfusion Apparatus
868.5880 Anesthetic Vaporizer
868.5895 Continuous Ventilator
868.5925 Powered Emergency Ventilator
868.5935 External Negative Pressure Ventilator
868.5955 Intermittent Mandatory Ventilation Attachment
870.1025 Arrhythmia Detector and Alarm
870.1750 External Programmable Pacemaker Pulse Generator
870.3535 Intra-aortic Balloon and Control System
870.3545 Ventricular Bypass (Assist) Device
870.3600 External Pacemaker Pulse Generator
870.3610 Implantable Pacemaker Pulse-Generator
870.3700 Pacemaker Programmers
870.4220 Cardiopulmonary Bypass Heart-Lung Machine Console
870.4320 Cardiopulmonary Bypass Pulsatile Flow Generator
870.4330 Cardiopulmonary Bypass On-Line Blood Gas Monitor
870.4360 Nonroller-Type Cardiopulmonary Bypass Blood Pump
870.4370 Roller-Type Cardiopulmonary Bypass Blood Pump
870.4380 Cardiopulmonary Bypass Pump Speed Control
870.5225 External Counter-Pulsating Device
870.5300 DC-Defibrillator Low Energy (Including Paddles)
876.5270 Implanted Electrical Urinary Continence Device
876.5630 Peritoneal Dialysis System and Accessories
876.5820 Hemodialysis System and Accessories
876.5860 High Permeability Hemodialysis System
876.5870 Sorbent Hemoperfusion System
876.5880 Isolated Kidney Perfusion and Transport System and Accessories
880.5130 Infant Radiant Warmer
880.5400 Neonatal Incubator
880.5410 Neonatal Transport Incubator
880.5725 Infusion Pump
882.5820 Implanted Cerebellar Stimulator
882.5830 Implanted Diaphragmatic/Phrenic Nerve Stimulator
882.5840 Implanted Intracerebral/Subcortical Stimulator For Pain Relief
882.5850 Implanted Spinal Cord Stimulator for Bladder Evacuation
882.5860 Implanted Neuromuscular Stimulator
882.5870 Implanted Peripheral Nerve Stimulator for Pain Relief
882.5880 Implanted Spinal Cord Stimulator for Pain Relief
884.1700 Hysteroscopic Insufflator
884.1730 Laparoscopic Insufflator
884.2660 Fetal Ultrasonic Monitor and Accessories
892.5050* Medical Charged-Particle Radiation Therapy System
892.5300* Medical Neutron Radiation Therapy System
892.5700* Remote Controlled Radionuclide Applicator System
892.5750* Radionuclide Radiation Therapy System
892.5900* X-ray Radiation Therapy System

*The device classifications specified previously with an asterisk include radiation treatment planning systems that are accessories to these device types.

B. Post Medical Device Amendments Class III Devices and Devices not yet Classified

Automated Blood Cell and Plasma Separator for Therapeutic Purposes
Cardioconverter, Implantable
Defibrillator, Automatic Implantable Cardioverter
Defibrillator, Implantable, Dual-Chamber
Device, Thermal Ablation, Endometrial
Kit, Test, Alpha-Fetoprotein for Neural Tube Defects
Lipoprotein, Low Density, Removal
Pulse-Generator, Dual Chamber, Implantable
Pulse-Generator, Program Module
Pulse-Generator, Single Chamber
Pulse-Generator, Single Chamber, Sensor Driven, Implantable
Pump, Drug Administration, Closed Loop
Pump, Infusion, Implanted, Programmable
Separator for Therapeutic Purposes, Membrane Automated Blood Cell/Plasma
Stimulator, Cortical, Implanted (for Pain)
Stimulator, Electrical, Implanted, for Parkinsonian Tremor
Stimulator, Sacral Nerve, Implanted
Stimulator, Spinal-Cord, Totally Implanted for Pain Relief
Stimulator, Subcortical, Implanted for Epilepsy
System, Pacing, Temporary, Acute, Internal Atrial Defibrillation
Ventilator, High Frequency

Dated: July 19, 1999.

Linda S. Kahan,

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

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