

III. Proposed Findings With Respect to Risks and Benefits

As required by section 515(b) of the act, FDA is publishing its proposed findings regarding: (1) The degree of risk of illness or injury designed to be eliminated or reduced by requiring that these devices have an approved PMA or a declared completed PDP, and (2) the benefits to the public from the use of the devices.

These findings are based on the reports and recommendations of the advisory committees (panels) for the classification of these devices along with any additional information that FDA has discovered. Additional information can be found in the following proposed and final rules published in the **Federal Register** on these dates: Anesthesiology devices, 21 CFR part 868 (44 FR 63292, November 2, 1979, and 47 FR 31130, July 16, 1982); cardiovascular devices, 21 CFR part 870 (44 FR 13284, March 9, 1979 and 45 FR 7903, February 5, 1980); and neurological devices, 21 CFR part 882 (43 FR 55639, November 28, 1978, and 44 FR 51725, September 4, 1979).

IV. Devices Subject to This Proposal

A. Indwelling Blood Oxyhemoglobin Concentration Analyzer (21 CFR 868.1120)

1. Identification

An indwelling blood oxyhemoglobin concentration analyzer is a photo electric device used to measure, in vivo, the oxygen carrying capacity of hemoglobin in blood to aid in determining the patient's physiological status.

2. Summary of Data

The Anesthesiology Device Classification Panel recommended that the indwelling blood oxyhemoglobin concentration analyzer intended to measure, in vivo, the oxygen carrying capacity of hemoglobin in blood to aid in determining the patient's physiological status be classified into class III based on the lack of published clinical data relating to the safety of, and the problems associated with this device. FDA agreed and continues to agree with the panel's recommendation that the device be classified into class III.

3. Risks to Health

a. *Inappropriate therapy*—Inaccurate measurement of the blood oxyhemoglobin concentration may cause an incorrect diagnosis leading to inappropriate therapy.

b. *Thrombus or embolus formulation*—If the analyzer materials

are incompatible with the blood, thrombus or embolus (clot) formation may result.

c. *Electrical shock*—If the device is not designed properly, the patient may receive an electrical shock.

d. *Vascular occlusion*—If the device sensor is too large, it may occlude the blood vessel in which it is placed, thus stopping the blood flow through that vessel.

B. Cardiopulmonary Bypass Pulsatile Flow Generator (21 CFR 870.4320)

1. Identification

A cardiopulmonary bypass pulsatile flow generator is an electrically and pneumatically operated device used to create pulsatile blood flow. The device is placed in a cardiopulmonary bypass circuit downstream from the oxygenator.

2. Summary of Data

The Cardiovascular Devices Classification Panel recommended that the cardiopulmonary bypass pulsatile flow be classified into class III because it is potentially hazardous to life or health even when properly used and because there are insufficient data to establish the safety and effectiveness of the device. FDA agreed and continues to agree with the panel's recommendation. The agency notes that the device has fallen into disuse and that the published data are not adequate to demonstrate the safety and effectiveness of the device.

3. Risks to Health

a. *Cardiac arrhythmias or electrical shock*—Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure and this may lead to iatrogenic complications.

b. *Blood damage*—If the materials, surface finish, cleanliness, or improper mechanical design of this device are inadequate, damage to the blood may result.

c. *Thromboembolism*—Inadequate blood compatibility of the materials used in the device, inadequate surface finish and cleanliness, or improper mechanical design may lead to potentially debilitating or fatal gas emboli to escape into the bloodstream.

C. Ocular Plethysmograph (21 CFR 882.1790)

1. Identification

An ocular plethysmograph is a device used to measure or detect volume

changes in the eye produced by pulsations of the artery, to diagnose carotid artery occlusive disease (restrictions on blood flow in the carotid artery).

2. Summary of Data

The Neurological Device

Classification Panel recommended that the ocular plethysmograph be classified into class III because it is used to detect the life-threatening condition that occurs when the brain does not receive adequate blood flow through a carotid artery.

3. Risks to Health

a. *Eye injury*—Excessive pressure can damage the eye.

b. *Misdiagnosis*—The device may misdiagnose the presence or absence of carotid artery occlusion because of a poor relationship between pulsatile arterial blood flow changes and the degree of occlusion.

c. *Infection*—Eye cups that are not sterile can cause infections.

V. PMA Requirements

A PMA for these devices must include the information required by section 515(c)(1) of the act. Such a PMA should also include a detailed discussion of the risks identified previously, as well as a discussion of the effectiveness of the device for which premarket approval is sought. In addition, a PMA must include all data and information on: (1) Any risks known, or that should be reasonably known, to the applicant that have not been identified in this document; (2) the effectiveness of the device that is the subject of the application; and (3) full reports of all preclinical and clinical information from investigations on the safety and effectiveness of the device for which premarket approval is sought.

A PMA should include valid scientific evidence "obtained from well-controlled clinical studies, with detailed data," in order to provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 CFR 860.7(c)(2)).

Applicants should submit any PMA in accordance with FDA's "Premarket Approval (PMA) Manual." This manual is available upon request from FDA, Center for Devices and Radiological Health, Division of Small Manufacturers Assistance (HFZ-220), 1350 Piccard Dr., Rockville, MD 20850. This manual is also available on the Internet at <http://www.fda.gov/cdrh>.

VI. PDP Requirements

A PDP for any of these devices may be submitted in lieu of a PMA, and must