#1302

BYPASS BLOOD PUMP

Public Citizen

Buyers Up • Congress Watch • Critical Mass • Health Research Group • Litigation Group

Ralph Nader, Founder

July 21, 1993

Dockets Management Branch (HFA-305)
Food and Drug Administration, rm. 1-23
12420 Parklawn Drive
Rockville, MD 20850

RE: Opposition to Reclassification of Nonroller-Type Cardiopulmonary Bypass Blood Pump, Docket No. 93M-0150.

Public Citizen's Health Research Group submits the following comments regarding the reclassification of the non-roller type cardiopulmonary bypass blood pump. Because the device is life-supporting and life-sustaining, functioning as a "substitute heart" during open-heart surgery, the FDA Circulatory Devices Panel classified it as a Class III device in 1979 (the more commonly used roller-type pump, used for transporting blood since the 1920s,[1] was classified as a class II device). FDA is now calling for safety and effectiveness data from manufacturers of the nonroller-type devices, and is also announcing (as required by law) that interested persons may request their reclassification. We are opposed to the reclassification of the nonroller-type blood pumps from class III to Class II. Although the roller-type device is in class II, we believe that it should have been characterized as a class III device. We presume that FDA placed it in class II because it was very widely used, and on the market for nearly 50 years. Thus, there was sufficient safety and effectiveness data available to allow manufacturers to forego further studies. However, if roller-type blood pumps were new devices being classified today, they would likely be characterized as class III devices. We urge that nonroller-type blood pumps remain in class III for the following reasons:

THE FUNCTION OF THESE DEVICES IS TO PUMP THE PATIENT'S ENTIRE BLOOD VOLUME DURING HEART SURGERY.

As stated by the Code of Federal Regulations, a device is in Class III if "insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of

[1] Dorson WJ, Loria IV JB. Heart-lung machines. In: Webster JG ed. Encyclopedia of medical devices and instrumentation, vol. 3. New York: John Wiley & Sons, 1988:1451-1457.

its safety and effectiveness or to establish a performance standard to provide such assurance and if, in addition, the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury." 21 CFR section 860.3. During cardiopulmonary bypass, the blood pump replaces the heart function. The pump plays a major role in keeping the brain and other tissues perfused and viable.[2] A pump failure would thus be analogous to a cardiac arrest. It is difficult to imagine a device which is more life-supporting and life-sustaining than a blood pump.

The literature contains a report of two recent episodes, where the failure of a centrifugal (nonroller) bypass pump allowed retrograde (reverse) blood flow in the arterial tubing (this could not occur with failure of the roller-type pump). The negative flow created a hemodynamic siphon, which drew air into the circuit. "The flow occurs so fast that the perfusionist cannot place a clamp on the arterial line fast enough to prevent a 'siphon' effect from sucking blood out of the aorta and air into the aorta," with disastrous potential consequences. "Mock circulatory studies in the laboratory show that retrograde flows can begin in as little as 540 ms [approx. 1/2 second] after the pump is turned off. This flow can attain a value of 2.5 L/min after another 470 ms."[3] Thus, the failure of the pump can cause a rapid and massive air embolism, resulting in cerebral dysfunction, stroke, coma, or death.[4]

PROPER PUMP DESIGN IS CRITICAL IN ENSURING THE SAFETY AND EFFECTIVENESS OF THE DEVICE.

According to the Encyclopedia of Medical Devices and Instrumentation, Vol. 3, all blood pumps should follow certain design criteria:

1. The pump should be able to move blood at flow rates up to 10L/min against a maximum pressure of 180 mm Hg (24 kPa).

2. The pump should be designed to minimize clotting and thrombus formation. All blood-contacting surfaces should either be biocompatible or be coated with a biocompatible substrate (one of the major advantages of the roller pump is that the only blood-contacting surface is the tubing, thereby eliminating the biocompatability problem and eliminating areas of stagnation). All contacting surfaces should be smooth, no areas of stasis should be allowed, and the pump should not promote the formation of gas emboli. Lastly, there should be no areas of high temperature (hot

---

[2] id.

[3] Kolff J, et al. Beware centrifugal pumps: not a one-way street, but a potentially dangerous siphon. Ann Thorac Surg 1990; 50(3):512.

[4] Weiland AP, Walker WE. Physiologic principles and clinical sequelae of cardiopulmonary bypass. Heart & Lung 1986;15(1):34-9.

spots) in contact with the blood.

3. The pump should be readily dismantled and easily sterilizable. Optimally, all blood-contacting surfaces should be disposable.

4. The calibration of the pump should be accurate and reliable for many hours of continued use.

5. The pump should be automated for normal use, but should contain a manual mode of operation in case of power failure.

6. The output of the pump should be independent of the resistance of the circuit being perfused.

7. Excessively high shear stresses and/or turbulent flow of the blood must be avoided. At shear stresses above 100-200 Pa, lysing (destruction) of red blood cells is proportional to the shear stress and excessive hemolysis occurs. At lower shear stresses, sublethal damage reduces the life span of red cells and damages both platelets and white blood cells.[5]

Failure to adhere to each of these design criteria could lead to serious complications in addition to embolism, retrograde perfusion and inadequate tissue perfusion already mentioned. Because blood cells are extremely fragile and susceptible to trauma, alteration in blood composition occurs when blood comes into contact with a blood pump. However if the pump design is defective, this process may be aggravated, causing a patient to suffer from abnormal bleeding problems, anemia, clot formation, and lung and kidney problems postoperatively. As stated in the New England Journal of Medicine, "The use of pump-oxygenator systems to facilitate open-heart surgery has been associated with a complex array of postoperative clinical sequelae, including coagulopathies [clotting disorders]; a systemic inflammation-like reaction that is characterized by increased capillary permeability, increased accumulation of interstitial fluids, leukocytosis, and fever; and profound organ dysfunction, which is particularly manifest in the pulmonary, renal, and central nervous systems."[6] Furthermore, the frequency and severity of adverse effects increases with the length of time the patient is on the pump.[7] If design is defective, a patient may remain on bypass much longer than anticipated, increasing his/her chances of sustaining adverse effects.

---

[5] Dorson, note 1.

[6] Chenoweth DE, Cooper SW, Hugli TE, et al. Complement activation during cardiopulmonary bypass. N Engl J Med 1981; 304:497-503.

[7] Westaby S. Complement and damaging effects of cardiopulmonary bypass. Thorax 1983;38:321-5.

RECLASSIFICATION OF THE BLOOD PUMPS INTO CLASS II WOULD ALLOW MANUFACTURERS TO AVOID CONDUCTING ANY SAFETY AND EFFECTIVENESS TESTS.

Industry is requesting the reclassification of the nonroller-type blood pumps from class III to class II. Class II devices are defined in the Code of Federal regulations as follows: "'Class II' means the class of devices that are or eventually will be subject to the requirements of a performance standard promulgated in accordance with section 514 of the act. A device is in class II if general controls alone are insufficient to provide reasonable assurance of its safety and effectiveness and there is sufficient information to establish a performance standard to provide such assurance." 21 CFR section 860.3(c)(2).

There is no performance standard in place to provide adequate assurance of the safety and effectiveness of the nonroller-type blood pump. Although the regulation does indicate that a device may be placed in class II if it "eventually will be subject to the requirements of a performance standard," this standard may never be established, judging by the fact that there have been no performance standards established for class II devices thus far. Thus, the devices will be completely unregulated in terms of their safety and effectiveness, an unacceptable situation when considering the serious risks posed by these devices.

In conclusion, we strongly oppose the reclassification of the nonroller-type cardiopulmonary bypass blood pump because a prospective, randomized, controlled clinical trial using a roller pump as the control (called for in FDA's Federal Register notice) must be performed in order to adequately evaluate the safety and effectiveness of the device. Such a trial will provide the necessary evidence in determining whether the nonroller-type pump is safer, equally as safe, or less safe than the roller-type pump. Placing the device in class II will allow manufacturers to avoid conducting these critical studies, and possibly expose the public to unsafe devices.

Sincerely,

Joanne C. Mott, R.N., J.D.
Health Research Group
Public Citizen

Sidney M. Wolfe, M.D.
Director, Health Research Group
Public Citizen