



MacoProductions S.A.S.  
Attention: Ms. Heather Pratt  
Macopharma USA  
3675 Crestwood Parkway, Suite 260  
Duluth, GA 30096

November 15, 2017

Re: BK160095  
Device Name: MacoMix HM20 and Hemolog 6  
Regulation Number: 21 CFR 864.9195  
Regulation Name: Blood Mixing Devices and Blood Weighing Devices  
Regulatory Class: II  
Product Code: MYJ  
Dated: July 17, 2017  
Received: July 18, 2017

Dear Ms. Pratt:

*This letter corrects our substantially equivalent letter of August 11, 2017.*

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to a legally marketed predicate device marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS)

regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

If you have questions about this letter, please contact Cherry Geronimo, Regulatory Project Manager, at (240) 402-9555 or [cherry.geronimo@fda.hhs.gov](mailto:cherry.geronimo@fda.hhs.gov).

Sincerely,

Jay S. Epstein, MD  
Director  
Office of Blood Research and Review  
Center for Biologics Evaluation and Research

Enclosure  
Indications For Use

**Indications for Use**

510(k) Number: BK160095

Device Name: MacoMix HM20 and Hemolog 6

Indications for Use:

The MacoMix HM20 device and optional Hemolog 6 software system is an automated blood mixer used during blood donation to mix the anti-coagulant contained in the blood bag with the whole blood collected during donation and automatically clamping the tube when the preset target volume has been reached.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CBER, Office of Blood Research and Review

\_\_\_\_\_  
Division Sign-Off, Office of Blood Research and Review