October 26, 2023

Jiangsu MaxF Electric Appliance Co., Ltd
% Cassie Lee
Official Correspondent
Share Info (Guangzhou) Medical Consultant Ltd
No. 1919-1920, Building D3, Minjie Plaza
Shuixi Road, Huangpu District
Guangzhou, Guangdong 510000
China

Re: K230500
Trade/Device Name: Air Compression Therapy Recovery System (model: MF-AWI, MF-AWI.LED.A-801, MF-AWI.LED.B-801, MF-AWI.OLED.A-601, MF-AWI.LED.A-601, MF-AWI.LED.B-601, MF-AWI.OLED.A-401, MF-AWI.LED.A-401, MF-AWI.LED.B-401)
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: August 10, 2023
Received: August 11, 2023

Dear Cassie Lee:

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 legally marketed predicate devices 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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