FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

UNITED PARCEL SERVICE
SIGNATURE REQUIRED

November 21, 2019

Michael Whitehurst, CEO
MiBo Medical Group
2526 Manana Road, Suite 105
Dallas, Texas 75220

Dear Mr. Whitehurst:

The Food and Drug Administration has completed evaluation of your firm's corrective actions in response to our Warning Letter (CMS #558900, November 20, 2018). Based on our evaluation, it appears that your firm has addressed the violations contained in this Warning Letter. Future FDA inspections and regulatory activities will further assess the adequacy and sustainability of these corrections.

This letter does not relieve you or your firm from the responsibility of taking all necessary steps to assure sustained compliance with the Federal Food, Drug, and Cosmetic Act and its implementing regulations or with other relevant legal authority. The Agency expects you and your firm to maintain compliance and will continue to monitor your state of compliance. This letter will not preclude any future regulatory action should violations be observed during a subsequent inspection or through other means.

Sincerely,

Jessica Mu

Digitally signed by Jessica Mu
DN: cn=Jessica Mu, o=OMDRHO Division 3/W, ou=Office of Regulatory Affairs, email=jessica.mu@fda.hhs.gov, c=US
Date: 2019.11.21 09:51:35 -08'00'

Jessica Mu, Director of Compliance
Medical Device & Radiological Health Operations
Division 3/West

U.S. Food and Drug Administration
Office of Medical Device & Radiological Health Operations
Division 3/W
19701 Fairchild
Irvine, CA 92612
www.fda.gov