DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Room 3208 Building 32
Silver Spring, MD 20993-0002

Flotec, Inc.
c/o Brian R. Davidson, President
7625 West New York Street
Indianapolis, IN 46214

Re: **Small Business Decision Number: SBD168252**
FDA User Fee Organization Number: **70098**
FY 2016 MDUFA Small Business Qualification
Approval Date: October 28, 2015
Expires: September 30, 2016

Dear Mr. Davidson:

The Food and Drug Administration's (FDA's) Small Business Determination (SBD) team has completed the review of your application eligibility as Small Business under the Medical Device User Fee Act (MDUFA). I am pleased to inform you that your firm qualifies under MDUFA as a Small Business for a reduced or waived fee for medical device submissions made during the fiscal year 2016.

Please include your Small Business Decision Number (see above) whenever you submit a Medical Device User Fee Coversheet (Form FDA 3601). This form is available at: http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFeeandModernizationAct/ucm155274.htm When completing the User Fee Coversheet, you must locate your organization with the organization number **70098** stated in this letter. Your organization number, SBD number, and Business name and address must correspond to the information located above in this letter.

If you are registering as a new user to the User Fee System, please use the organization number assigned to you in this letter to register as an existing organization. If you currently have a User Fee account and the organization number in your profile does not match this organization number, please contact the User Fees Help Desk for further assistance at 301-796-7200 or at userfees@fda.gov.

Your Small Business status expires at the close of business September 30, 2016. FDA will provide information on how to qualify as a Small Business for FY2017 in a FEDERAL REGISTER Notice to be published on or about August 1, 2016. We will also provide this information on our MDUFA website at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm

Sincerely,

Gene W. Allen

Gene W. Allen
Public Health Advisor
Premarket Programs Branch
Division of Industry and Consumer Education
Office of Communication and Education
Center for Devices and Radiological Health
U.S. Food and Drug Administration