



<b>Document Title:</b>		<b>Doc. No.:</b>	<b>Letter to File</b>
FCC label Placement Justification LTF		<b>Revision:</b>	<b>NA</b>
<b>Product:</b>	Fecobionics AR-100 Probe		
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## Fecobionics Probe FCC Label Placement

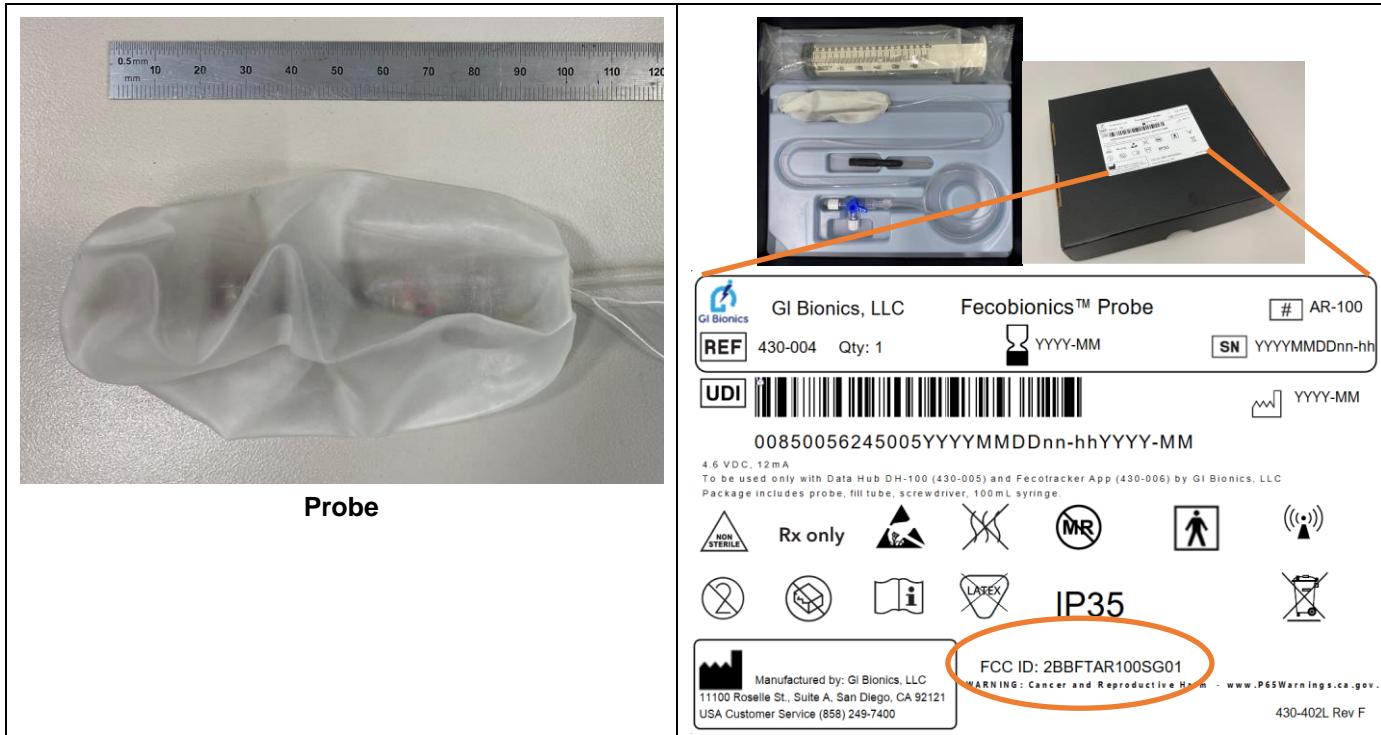
**To:** Letter to File  
**From:** Fred Field  
**Regarding:** Justification for alternative placement of FCC Label for Fecobionics probe  
**Date:** 3-18-25

The Fecobionics AR-100 Probe is a disposable medical device that wirelessly transmits sensor data to a Data Hub (DH-100), which wirelessly communicates with a laptop computer running a custom app. The system produces a real-time display of probe sensor data and is used to assess defecation deficiencies. The probe is designed with a shape and flexibility that simulates feces. After it is inserted into the rectum of a patient, the outer bag is inflated to provide selected amounts of bulk. The probe sensors are used to measure the degree that the patient's anatomy can act on the probe during defecation and certain clinical movements. The probe has a diameter of 1.0 cm so that it can be inserted easily into the rectum and a flexible length of 10.0 cm to simulate the bulk of feces. The sensors are arrayed on a flex-rigid printed circuit board that is over molded with silicone. The probe body is covered by a silicone bag that is filled with saline after insertion.

The probe's small size, the inherent difficulty of attaching a label to silicone rubber, and the fact that the silicone bag would obscure any label placed along the body of the probe necessitate that all label information, including the FCC information must be placed on the product packaging. Each probe is provided in an ESD protected box with a label indicating various information about the device including the FCC ID information (see figure below).



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Signature of Authorized Individual:	
Printed Name:	Ghassan Kassab
Title of authorized signature:	General Manager
Date	3/18/2025