

Vicki Albertson

From: oetech@fcc.gov
Sent: Tuesday, April 12, 2022 8:09 AM
To: Vicki Albertson
Subject: Response to Inquiry to FCC (Tracking Number 249851) (TCB)

Importance: High

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Inquiry on 04/08/2022 :

Inquiry:

An applicant is obtaining an FCC approval for their implantable pulse generator under FCC 15.247. They are seeking an exception from having to label the product directly and have provided the following justification:

In its intended use, the IPG remains in sterilized packaging and remains in "storage mode" with all radios off until it is unsealed by the surgeon and ready for implant into the patient. Once implanted, any FCC info on the IPG will not be available. The IFU and packaging are the most reliable way to find the FCC ID info as you won't be able to see the IPG while it's inside the box nor after it's implanted. There is a special Id Tag that can only be seen via X-Ray. This information can be used to trace the IPG information which would tie back to any FCC ID info. Adding additional text to the outside of the IPG while technically achievable, it has other FDA and medical implications that make the process more complex so we would like to comply strictly through the FCC ID listed on the packaging and IFU.

Please confirm if they can place the label on the packaging and in the user manual rather than on the product itself.

Thanks

FCC response on 04/12/2022

Hello,
Yes, we will accept your proposal.

Attachment Details:

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