

Subject: Response to Inquiry to FCC (Tracking Number 155393)

Date: Thursday, May 13, 2021 at 8:40:28 AM Pacific Daylight Time

From: oetech@fcc.gov

To: Rizwan Bashirullah

EXTERNAL

Inquiry on 02/04/2021 :

Inquiry:

Dear FCC,

As requested, please find the attached reports:

- "ER-0637_Rev A_SAR Compliance Characterization.pdf" and
- EMC_FCC_104106572MPK-001C-PART2p1093_and_RSS102_CHARGER_2020APR19.pdf"

detailing the RF exposure characterization results for the following electronic medical equipment:

- FCC ID:2AVN4-31102 - Implant Charger
- FCC ID:2AVN4-21101 - Implant

Regards

Rizwan Bashirullah
Galvani Bioelectronics

FCC response on 02/04/2021

Is there a previous KDB inquiry you are responding to? Is this a response to an audit?
This reviewer does not understand the basis for the submitted information.

--Reply from Customer on 02/04/2021---

Dear FCC KDB,

Could you please advise if the attached two reports sufficient to demonstrate compliance with RF exposure requirements for an implant device with a charger?

The to-be certified implant device, FCC ID: 2AVN4-21101. obtains power through wireless power transfer (WPT). SAR evaluation for the to-be certified 6.78 MHz inductive charger, FCC ID: 2AVN4-31102, is included in the submitted report, file name: ER-0637 _Rev A _SAR Compliance Characterization.pdf.

SAR evaluation for the Bluetooth radios contained in the implant device and its charger was performed at Intertek and documented in the test report, report number: 104106572MPK-001C, submitted file name:

A user manual is attached for your reference.

Thank you very much and we look forward to your approval.

-Rizwan

FCC response on 02/10/2021

Thank you for the clarification. The TCB must submit an operational description exhibit for any certification filing. Can you provide that exhibit to this inquiry? We would like to review it. Subsequent TCB processing may still require a PAG filing.

--Reply from Customer on 02/12/2021---

Dear FCC KDB,
Please find the attached operational description documents.
Thank you

-Rizwan B

FCC response on 05/13/2021

We apologize for the long delay in responding. We believe both the implant and charger will meet RF exposure limits but have not come to a consensus on test protocols. If you have not already done so, we believe consultation with a TCB is warranted.

Attachment Details:

[SAR characterization report](#)

[RF Exposure Exhibit](#)

[AW-0817 Rev C Galvani System Patient Manual Part 1](#)

[AW-0817 Rev C Galvani System Patient Manual Part 2](#)

[Gen1 System Overview](#)

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