From: Rachel Zhang
To: tcb_admin@intertek.com; Anderson Soungpanya Intertek
Subject: FW: Response to Inquiry to FCC (Tracking Number 313065)
Date: Wednesday, May 18, 2022 10:03:00 AM

Hi Cliff and Anderson,
We just heard back from FCC KDB inquiry that placing the FCC on Pod tray is acceptable. Though we have already used E-labeling for our OP5 SAW Pod, but this do give us a guidance for other products later. Thanks!

Rachel

From: oetech@fcc.gov <oetech@fcc.gov>
Sent: Wednesday, May 18, 2022 9:56
To: Rachel Zhang <rozhang@insulet.com>
Subject: Response to Inquiry to FCC (Tracking Number 313065)

Inquiry on 05/16/2022 :

Inquiry:

Insulet Corporation would like to request guidance surrounding the application of labeling requirements for Identification of equipment per 47 CFR 2.925(f). Insulet has received inconsistent guidance from Third Party Laboratory Testing providers during FCC certification of our Omnipod 5 Pod, specifically whether we must directly mark our single-use, sterile, disposable Omnipod 5 Pod with the FCC ID. One test house provided feedback that the Omnipod 5 device does not qualify for the exemption for FCC ID under 47 CFR 2.925(f) because the exemption regarding impractical use is only for implantable medical devices, while another test house believes we did meet the exemption requirement both considering size and use.

FCC response on 05/18/2022

For the circumstance of The Omnipod 5, a surgically invasive, single use, sterile medical device product, putting the FCC ID on the pod tray lid of the sterile tray which accompanies every Omnipod 5 Pod, is acceptable. This is based on the fact that this is a single use medical device and having the FCC ID displayed on the sterile tray in view of users along with FDA labelling, in FCC Staff's opinion meets the intent of § 2.925 (d) (2) Identification of equipment.

Attachment Details:

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