October 25, 2022

Leigh Spotten
Director, Regulatory Affairs
Karl Storz SE and Co KG
2151 E. Grand Ave.
El Segundo, CA 90245

Sent via email to: leigh.spotten@karlstorz.com

Dear Petitioner:

Your submission requesting that the Commissioner to take all administrative actions required for reclassification or the medical devices associated with Product Code OAY; FDA regulatory classification details of which as on May 17, 2019 was received and processed under CFR 10.30 by this office on 10/25/2022.

It was assigned docket number FDA-2022-P-2644. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Karen P. Malvin -S
Digitally signed by Karen P. Malvin -S
Date: 2022.10.25 15:15:05 -04'00'

Karen Malvin
Acting Director
Dockets Management Staff
FDA/Office of Operations (OO)