July 18, 2020

GBUK Group Ltd
Attn: Dr. Steve Curran
Regulatory Affairs Manager
Woodland House
Blackwood Hall Business Park
North Duffield
Selby, North Yorkshire, YO8 5DD, UK

Sent via email to: lucy.islip@gbukgroup.com

Re: Citizen Petitions – Docket Numbers: FDA-2020-P-0725 and FDA-2020-P-0734

Dear Petitioner:

This is an interim response to your two petitions, dated and received by the Food and Drug Administration (FDA) on February 11, 2020, and docketed separately at FDA-2020-P-0725 and FDA-2020-P-0734. In the petitions, you requested FDA to exempt from our instructions for use (IFU) requirements certain medical devices, including accessories, that you listed in premarket 510(k) submissions K170371 and K170900.

Because your petitions raise issues requiring further review and analysis by agency officials, FDA is unable to reach a decision on either of your petitions at this time. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petitions as soon as we have reached a decision on your requests.

If you have any questions about this interim response, please contact John Maiers of our Office of Policy at (301) 796-0343.

Sincerely yours,

Ellen J. Flannery -S

Digitally signed by Ellen J. Flannery -S
Date: 2020.07.18 16:30:09 -04'00'

Ellen J. Flannery, JD
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and
Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov