DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

February 11, 2020

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

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

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to remove the requirement for adequate directions for use to be supplied with the medical devices and accessories listed in premarket submission K170900 was received by this office on 02/11/2020.

It was assigned docket number FDA-2020-P-0734. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby

Digitally signed by
Dynna Bigby
Date: 2020.02.12
09:39:08 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)