September 23, 2022

Endolumik Inc.
Mara McFadden
Chief Executive Officer
364 Patteson Dr. #293
Morgantown, WV 26505

Re: Q221857
Trade/Device Name: Gastric Calibration Tube
Received: August 25, 2022

Dear Mara McFadden:

The Food and Drug Administration (FDA) has received the above submission requesting entrance into the Safer Technologies Program ("STeP"). The proposed indications for use is: "the Endolumik Gastric Calibration Tube is indicated for use in gastric and bariatric surgical procedures for the application of suction, stomach decompression, drainage of gastric fluids, irrigation, to test for leaks, to provide visualization of the tube position, and to serve as a sizing and measurement guide". We are pleased to inform you that your device meets the eligibility factors and has been included in STeP for your proposed indications. Please refer to the FDA guidance document entitled "Safer Technologies Program for Medical Devices" for more information regarding the program, available at https://www.fda.gov/media/130815/download.

Information on the available mechanisms for obtaining feedback from the Agency on device development for devices in STeP is available in the FDA guidance document for STeP referenced above. Sponsors of devices included in STeP also have the option to request feedback from FDA through mechanisms that are available for devices, generally. These mechanisms are described in the FDA guidance document entitled "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program", available at https://www.fda.gov/media/114034/download. When submitting any new requests for feedback, please reference Q221857. Any new submission or Q-Sub amendment must be provided as an eCopy. For more information about FDA's eCopy program, including the technical standards for an eCopy, refer to the guidance document, "eCopy Program for Medical Device Submissions" at https://www.fda.gov/media/83522/download. In addition, we strongly encourage you to visit FDA's eSubmitter website at https://www.fda.gov/industry/fda-esubmitter/cdrh-esubmitter-program for assistance developing an eCopy consistent with the technical standards prior to sending a submission to FDA.

The submission should include the FDA reference number for this Q-Sub , and should be submitted to the following address:

U.S. Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
IDE Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

You are reminded that inclusion in STeP does not change the requirements for approval of an application for an Investigational Device Exemption (IDE) under section 520(g) or marketing authorizations under section 515(c), 510(k), or 513(f)(2) of the Federal Food, Drug, and Cosmetic Act. Additionally, clinical data submitted to support any marketing submission for your device should constitute valid scientific evidence (21 CFR 860.7). You are further advised that inclusion in STeP does not guarantee approval of a future IDE application or supplement or that a future marketing submission will ultimately be approved, cleared, or granted.

If you have any questions, please contact Mustafa Mazher at 301-796-0149 or Mustafa.Mazher@fda.hhs.gov.

Sincerely,

Glenn B. Bell -S

Glenn B. Bell, Ph.D.
Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health