November 5, 2020

RE: Regulatory Status and Discontinuation of PCF-H180AI and PCF-H180AL Video Colonoscopes

Dear Valued Customer:

This letter is provided on behalf of Olympus Medical Systems Corporation (OMSC) and is intended to provide information about the EVIS EXERA II PCF-H180AI and PCF-H180AL Video Colonoscopes. The PCF-H180AI and PCF-H180AL colonoscopes are used with other supporting equipment for endoscopy and endoscopic surgery within the lower digestive tract.

Olympus previously notified you on August 31st, 2020 of the review of past changes to the company's flexible endoscopes. This letter is notifying you of two additional flexible endoscope models affected by this review, which have undergone past changes for which we did not submit a 510(k), but now believe a better approach would have been to submit a 510(k).

OMSC has undertaken a review of past changes to the company's flexible endoscopes and has decided to take action with regard to the PCF-H180AI and PCF-H180AL colonoscopes as discussed below. As you may know, not every modification to a medical device requires the submission of a new premarket notification (commonly referred to as a "510(k)") to FDA. In accordance with FDA regulations and guidance, it is up to the manufacturer to determine if a change is significant, thereby triggering the need to submit a new 510(k) to FDA, or if the change is minor and may be documented in the manufacturer's quality system.

OMSC made certain changes to its flexible endoscopes in the past and analyzed those changes using then-available FDA guidance. In some cases, OMSC determined, at that time, a change required a new 510(k); in other cases, the company determined that a change did not trigger the need for a new 510(k) submission.

OMSC recently conducted a retrospective review of past changes to its portfolio of flexible endoscopes (from 1991 through 2018), applying current FDA guidance for assessing device modifications, including FDA's 2017 guidance on this topic. That review validated our current process and found that the company has been appropriately assessing changes to its endoscopes over the past several years. However, following the review, OMSC decided that as a result of some earlier changes (all of which were implemented between 1991 and 2013), it would submit "catch up" 510(k)s for certain endoscope models and discontinue sales for other models.

Sales of new PCF-H180AI and PCF-H180AL colonoscopes were discontinued in January 2019, and OMSC will not be submitting a "catch-up" 510(k) for these models. Accordingly, OMSC is writing to inform you that all sales of PCF-H180AI and PCF-H180AL colonoscopes, including but not limited to Certified Pre-Owned, will be discontinued as of October 2020. OMSC will continue to service these devices until the end-of-service date, March 2026.

Patient safety remains our top priority. OMSC has and will continue to conduct regular post market surveillance according to applicable standards and guidance, including review and investigation of complaints and adverse events. Currently, we are not aware of any signals that would suggest these devices pose unacceptable risks to patients or users versus the benefits that you have come to trust and rely upon. Consequently, at this time, we do not intend to recall or take other corrective actions for these devices. Of course, we recommend that you follow all instructions for such devices, including the device reprocessing instructions, and report to Olympus and/or the U.S. Food and Drug Administration (FDA) any product malfunctions or complaints. The FDA is aware of the actions described in this letter.

Sincerely,

Ross D. Segan, MD, MBA, FACS
Chief Medical Officer
Olympus Corporation