August 31, 2020

Dear Valued Customer:

This letter is provided on behalf of Olympus Medical Systems Corporation (OMSC) and is intended to provide information about certain flexible endoscopes manufactured by OMSC that your institution may be using. OMSC has undertaken a review of past changes to the company's flexible endoscopes and has decided to take a number of actions 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.

At the end of this letter is a list of models affected by this review that you have purchased.

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 FDA any product malfunctions or complaints.

OMSC has presented to FDA the findings of this review as well as the following plan of action developed by OMSC. For those models that the company intends to continue selling in the United States, OMSC will be submitting new 510(k)s to FDA. For other models, OMSC has discontinued new sales but will continue to service devices already in use until the end-of-service date, as indicated immediately below.

Sincerely,

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