DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181509

Device Name
Endorate™ Valves Sets

Indications for Use *(Describe)*
The disposable Endorate™ valves sets consists of one suction valve, one air/water valve and one biopsy valve.

The Endorate™ Disposable Suction valve is used to control the suction function of an endoscope (for Olympus 160 series Endoscope) during a GI Endoscopic procedure.

The Endorate™ Disposable Air/Water valve is used to control the air/water function of an endoscope (for Olympus 160 series Endoscope) during a GI Endoscopic procedure.

The Endorate™ Disposable biopsy valve is used to cover the endoscope biopsy port during an endoscopy procedure. In addition, the valve provides access for endoscopic device passage and exchange, helps maintain insufflation and minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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