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)*
K182998

Device Name
Andorate™ Auxiliary Water Connector

Indications for Use *(Describe)*
The Andorate™ Auxiliary Water Connector (Model GAR027) is used in conjunction with irrigation tubing (not supplied), intended to provide irrigation via irrigation fluids such as sterile water supplied to the Olympus 160 series endoscope during gastrointestinal endoscopic procedures when used in conjunction with an irrigation pump.

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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