

K 970372

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Attachment E

510(k) Summary for Endoscope Nozzle Repair Kits

Applicant: P. E. A. Products, Inc.
10969 McCormick Road
Hunt Valley, Maryland 21031
Contact: Mr. Daniel M. Honeywell
Phone: (800) 285-5959

Predicate Device: Olympus America, Inc. endoscope nozzles and set screws

Device Description: These endoscope nozzle replacement kits are intended for use in replacing the nozzle on 43 models of Olympus America, Inc. gastroscopes and colonoscopes. Each kit includes 6 nozzles, three set screws, sealant, and the necessary tools (#1 screw driver, tweezers, and magnifying glass) to replace the nozzle. Each kit will include only the nozzle size(s) and set screw size(s) appropriate for use with the Olympus of America, Inc. endoscope models currently being used by the purchaser.

Substantial Equivalence:

The nozzles, set screws, and sealant are the only kit components that are incorporated into the endoscope and come in contact with the patient. The premarket notification contains information and documentation that these components are substantially equivalent to those used by the original manufacturer in that they are for the same intended use and have the same technological characteristics. The remaining kit components (i.e., tools) are general purpose articles not regulated by FDA as medical devices. They are provided both as a convenience and as an assurance that the proper tools are used to replace the nozzle.

The applicant has extensive experience in the servicing and repair of endoscopes. This experience has demonstrated that nozzle replacement is easily performed and that proper nozzle alignment can readily be confirmed without the need for additional equipment.