

K162447 PENTAX Medical Endoscopic Ultrasound System, EG-3270UK Upper G.I. Video Scope (Convex Array Type) with EPK-i5010 Video Processor and HI VISION Preirus Ultrasound ScannerApr 13, 2017
224 days to decisionK162447 · Product code: **ODG** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k162447/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Ultrasound System, Gastroenterology-urology (ODG)
Date received	Sep 1, 2016
Decision date	Apr 13, 2017
Days to decision	224 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pentax of America, Inc.
Location	West Cadwell, NJ, US
Contact	Krishna Govindarajan
510(k) history	44 submissions · 44 cleared · 2012-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162447/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 1, 2026