

K021276 FG-36UX FIBER ULTRASOUND GASTROSCOPESep 12, 2002
143 days to decisionK021276 · Product code: **ODG** · Radiology
Source: <https://www.510kdatabase.net/k021276/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Ultrasound System, Gastroenterology-urology (ODG)
Date received	Apr 22, 2002
Decision date	Sep 12, 2002
Days to decision	143 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pentax Precision Instrument Corp.
Location	Mchenry, IL, US
Contact	PAUL SILVA
510(k) history	67 submissions · 67 cleared · 1979-2004

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