

K953876 PENTAX ULTRASOUND ENDOSCOPE MODEL FG-32UA (MODIFICATION)

Nov 24, 1995
109 days to decision

K953876 · Product code: **ODG** · Radiology
Source: <https://www.510kdatabase.net/k953876/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Ultrasound System, Gastroenterology-urology (ODG)
Date received	Aug 7, 1995
Decision date	Nov 24, 1995
Days to decision	109 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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Device record: <https://www.510kdatabase.net/k953876/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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