

**K971528 ENDOSCOPICALLY DELIVERABLE ULTRASOUND  
POINT PORBE SYSTEM (ENDOSCOPY)**Dec 12, 1997  
228 days to decisionK971528 · Product code: IYO · Radiology  
Source: <https://www.510kdatabase.net/k971528/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Apr 28, 1997
Decision date	Dec 12, 1997
Days to decision	228 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Fujinon, Inc.</b>
Location	Washington, DC, US
Contact	GARY A ADLER
510(k) history	30 submissions · 30 cleared · 1990-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k971528/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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