

K861358 PS SYSTEM WITH SD-200 DOPPLERJul 30, 1986
111 days to decisionK861358 · Product code: **ITX** · Radiology
Source: <https://www.510kdatabase.net/k861358/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Apr 10, 1986
Decision date	Jul 30, 1986
Days to decision	111 days
Third-party review	No

APPLICANT

Company	Johnson & Johnson Professionals, Inc.
Location	Raynham, MA, US
Contact	RAYMOND F CHASE
Website	https://www.jnj.com
510(k) history	206 submissions · 184 cleared · 1976-2000

Johnson & Johnson Professionals, Inc. is a medical device company based in Raynham, Massachusetts. The company specializes in surgical and orthopedic devices. The company has received FDA 510(k) clearances from total submissions between 1976 and 2000. Orthopedic devices and neurosurgical instruments represent core product categories. Notable cleared devices include hip and elbow prostheses, programmable valve systems, and aneurysm clips. The company is inactive and represents a historical regulatory record with no submissions in more than two decades. Explore the complete...

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Device record: <https://www.510kdatabase.net/k861358/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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