FDA 510(k) Premarket Notification

K952161 BIPOLAR COAGULATION INSTRUMENT

CLEARED

Jul 5, 1995
58 days to decision

K952161 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k952161/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	May 8, 1995
Decision date	Jul 5, 1995
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Johnson & Johnson Professionals, Inc.**
Location	Raynham, MA, US
Contact	JOHN D FERROS
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...