

K954021 EXTERNAL DRAINAGE SYSTEM (EDS AND EDS II)Oct 24, 1995
85 days to decisionK954021 · Product code: **JXG** · Neurology
Source: <https://www.510kdatabase.net/k954021/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shunt, Central Nervous System And Components (JXG)
Date received	Jul 31, 1995
Decision date	Oct 24, 1995
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Johnson & Johnson Professionals, Inc.
Location	Raynham, MA, US
Contact	ANNE M GRIFFIN
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...
