FDA 510(k) Premarket Notification

K870211 BONDEX* GLASS IONOMER CEMENT

CLEARED

Mar 18, 1987
57 days to decision

K870211 · Product code: **EMA** · Dental
Source: https://www.510kdatabase.net/k870211/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Jan 20, 1987
Decision date	Mar 18, 1987
Days to decision	57 days
Third-party review	No

APPLICANT

Company	**Johnson & Johnson Professionals, Inc.**
Location	Raynham, MA, US
Contact	LANDSMAN, MHS
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...