FDA 510(k) Premarket Notification

K842078 JOHNSON & JOHNSON FLAVORED ETCHING GEL

CLEARED

Jul 12, 1984
50 days to decision

K842078 · Product code: **KLE** · Dental
Source: https://www.510kdatabase.net/k842078/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	May 23, 1984
Decision date	Jul 12, 1984
Days to decision	50 days
Third-party review	No

APPLICANT

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