FDA 510(k) Premarket Notification

K935881 SPECIALTY SPONGES

CLEARED

Jan 31, 1994
53 days to decision

K935881 · Product code: **GDY** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k935881/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gauze/sponge, Internal, X-ray Detectable (GDY)
Date received	Dec 9, 1993
Decision date	Jan 31, 1994
Days to decision	53 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Mcneil Healthcare, Inc.**
Location	Waterford, CT, US
Contact	TIMOTHY D MCNEIL
510(k) history	19 submissions · 19 cleared · 1994-1994