FDA 510(k) Premarket Notification

K935940 GAUZE SPONGE

CLEARED

Jan 14, 1994
32 days to decision

K935940 · Product code: **EFQ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k935940/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gauze/sponge, Internal (EFQ)
Date received	Dec 13, 1993
Decision date	Jan 14, 1994
Days to decision	32 days
Third-party review	No
Summary / Statement	Statement
Other names	DRAIN SPONGE

APPLICANT

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