FDA 510(k) Premarket Notification

K922441 SURESEAL BANDAGE

CLEARED

Aug 10, 1993
445 days to decision

K922441 · Product code: **KGX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k922441/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tape And Bandage, Adhesive (KGX)
Date received	May 22, 1992
Decision date	Aug 10, 1993
Days to decision	445 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Gainor Medical Europe, Ltd.**
Location	Mcdonough, GA, US
Contact	GAINOR
510(k) history	13 submissions · 13 cleared · 1990-1994

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k922441/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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