FDA 510(k) Premarket Notification

K063458 3M TEGADERM CHG DRESSING

CLEARED

Apr 5, 2007
141 days to decision

K063458 · Product code: **FRO** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k063458/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Nov 15, 2006
Decision date	Apr 5, 2007
Days to decision	141 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**3M Company**
Location	White City, OR, US
Contact	MARIA RUIZ
Website	http://www.3m.com/
510(k) history	331 submissions · 322 cleared · 1976-2025

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k063458/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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