

K983163 BIATAIN FOAM DRESSINGDec 16, 1998
97 days to decisionK983163 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k983163/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Sep 10, 1998
Decision date	Dec 16, 1998
Days to decision	97 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Coloplast Corp.
Location	Marietta, GA, US
Contact	M. SYDNEY LILLY
510(k) history	54 submissions · 47 cleared · 1985-2025

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