FDA 510(k) Premarket Notification

CLEARED

K120828 BIATAIN SILICONE AG FOAM DRESSING - ADHESIVE: 3X3 INCHES, 4X4 INCHES, & 5X5 INCHES

Apr 5, 2012
17 days to decision

K120828 · Product code: **FRO** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k120828/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dressing, Wound, Drug (FRO)
Date received	Mar 19, 2012
Decision date	Apr 5, 2012
Days to decision	17 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Coloplast A/S**
Location	Mchenry, IL, US
Contact	REBEKA STOLTMAN
Website	http://www.coloplast.com/
510(k) history	71 submissions · 68 cleared · 1983-2023

Coloplast A/S is a Danish multinational medical device manufacturer based in McHenry, US. The company develops and markets devices for ostomy, urology, continence, and wound care. Coloplast has received FDA 510(k) clearances from total submissions since its first clearance in 1983. The company's regulatory portfolio is dominated by Gastroenterology & Urology devices, including catheter systems, guidewires, and access sheaths. The latest clearance on record dates to 2023, reflecting the company's historical engagement with FDA regulatory pathways. Notable cleared devices i...