FDA 510(k) Premarket Notification

K191536 Biatain Silicone Ag

CLEARED

Feb 21, 2020
256 days to decision

K191536 · Product code: **FRO** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k191536/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Jun 10, 2019
Decision date	Feb 21, 2020
Days to decision	256 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Coloplast A/S**
Location	Mchenry, IL, US
Contact	Kimberly Tokach
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...