FDA 510(k) Premarket Notification

K103568 RESTORELLE POLYPROPYLENE MESH

CLEARED

Dec 22, 2010
16 days to decision

K103568 · Product code: **FTL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k103568/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Dec 6, 2010
Decision date	Dec 22, 2010
Days to decision	16 days
Third-party review	No
Summary / Statement	Summary
Other names	RESTORELLE POLYPROPYLENE MESH

APPLICANT

Company	**Coloplast A/S**
Location	Mchenry, IL, US
Contact	JANELL A COLLEY
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...