FDA 510(k) Premarket Notification

CLEARED

K111881 VIRTUE MALE SLING SYSTEM AND ALEXIS(R) WOUND RETRACTOR KIT

Aug 17, 2011
47 days to decision

K111881 · Product code: **OTM** · General Hospital
Source: https://www.510kdatabase.net/k111881/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, For Stress Urinary Incontinence, Male (OTM)
Date received	Jul 1, 2011
Decision date	Aug 17, 2011
Days to decision	47 days
Third-party review	No
Summary / Statement	Summary

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...