FDA 510(k) Premarket Notification

CLEARED

K101297 VIRTUE VENTRAL URETHRAL ELEVATION SLING SYSTEM MODEL 50020

Jun 3, 2010
24 days to decision

K101297 · Product code: **OTM** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k101297/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, For Stress Urinary Incontinence, Male (OTM)
Date received	May 10, 2010
Decision date	Jun 3, 2010
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Coloplast A/S**
Location	Mchenry, IL, US
Contact	ANGELA BYLAND
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...