FDA 510(k) Premarket Notification

CLEARED

K083499 EXAIR ANTERIOR AND POSTERIOR PROLAPSE REPAIR SYSTEMS

May 8, 2009
164 days to decision

K083499 · Product code: **OTP** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k083499/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Pelvic Organ Prolapse, Transvaginally Placed (OTP)
Date received	Nov 25, 2008
Decision date	May 8, 2009
Days to decision	164 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...