FDA 510(k) Premarket Notification

K173527 Digitex Delivery Device

CLEARED

Feb 12, 2018
90 days to decision

K173527 · Product code: **PWI** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k173527/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrumentation, Surgical Mesh, Urogynecologic, Transvaginal Repair Of Pelvic Organ Prolapse (PWI)
Date received	Nov 14, 2017
Decision date	Feb 12, 2018
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Coloplast A/S**
Location	Mchenry, IL, US
Contact	Nikita Basandra
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...