FDA 510(k) Premarket Notification

K220420 Saffron Fixation System

CLEARED

Jun 10, 2022
116 days to decision

K220420 · Product code: **PBQ** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k220420/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fixation, Non-absorbable Or Absorbable, For Pelvic Use (PBQ)
Date received	Feb 14, 2022
Decision date	Jun 10, 2022
Days to decision	116 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Coloplast A/S**
Location	Mchenry, IL, US
Contact	Gayatri Ghadge
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...

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Device record: https://www.510kdatabase.net/k220420/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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