K112386 EXAIR ANTERIOR AND POSTERIOR PROLAPSE REPAIR SYSTEM

CLEARED

Sep 8, 2011
21 days to decision

K112386 · Product code: **OTP** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k112386/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Pelvic Organ Prolapse, Transvaginally Placed (OTP)
Date received	Aug 18, 2011
Decision date	Sep 8, 2011
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Coloplast Corp.**
Location	Marietta, GA, US
Contact	TIM CRABTREE
510(k) history	54 submissions · 47 cleared · 1985-2025