

**K112386 EXAIR ANTERIOR AND POSTERIOR PROLAPSE
REPAIR SYSTEM**Sep 8, 2011
21 days to decisionK112386 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k112386/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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