

K132061 RESTORELLE M, RESTORELLE XLAug 2, 2013
30 days to decisionK132061 · Product code: **OTO** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k132061/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Apical Vaginal And Uterine Prolapse, Transabdominally Placed (OTO)
Date received	Jul 3, 2013
Decision date	Aug 2, 2013
Days to decision	30 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

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