FDA 510(k) Premarket Notification

K122440 RESTORELLE L

CLEARED

Nov 19, 2012
101 days to decision

K122440 · Product code: **OTO** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k122440/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Apical Vaginal And Uterine Prolapse, Transabdominally Placed (OTO)
Date received	Aug 10, 2012
Decision date	Nov 19, 2012
Days to decision	101 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