K122968 NOVASILK MESH QTY 1 MODEL 93-6014, NOVASILK MESH QTY 3 MODEL 93-6015

CLEARED

Dec 18, 2012
84 days to decision

K122968 · Product code: **OTO** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k122968/

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	Sep 25, 2012
Decision date	Dec 18, 2012
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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