K053361 MODIFICATION TO: MINIMESH POLYPROPYLENE MESH

CLEARED

Feb 6, 2006
66 days to decision

K053361 · Product code: **OTO** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k053361/

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	Dec 2, 2005
Decision date	Feb 6, 2006
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Mpathy Medical Devices, Ltd.**
Location	Fairfield, CT, US
Contact	LOUIS J MAZZARESE
510(k) history	6 submissions · 6 cleared · 2004-2009