FDA 510(k) Premarket Notification

K161038 PK Morcellator

CLEARED

Oct 7, 2016
177 days to decision

K161038 · Product code: **GEI** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k161038/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Apr 13, 2016
Decision date	Oct 7, 2016
Days to decision	177 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Gyrus Acmi, Inc.**
Location	Westborough, MA, US
Contact	GRAHAM A.L. BAILLIE
Website	https://www.olympusmedical.com
510(k) history	42 submissions · 42 cleared · 2007-2026