FDA 510(k) Premarket Notification

K123141 ENSEAL TRIO TISSUE SEALING DEVICE

CLEARED

Oct 25, 2012
20 days to decision

K123141 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k123141/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Oct 5, 2012
Decision date	Oct 25, 2012
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ethicon Endo-Surgery, LLC**
Location	Blue Ash, OH, US
Contact	EMILY KREUTZKAMP
Website	https://www.jnjmedtech.com
510(k) history	70 submissions · 70 cleared · 2006-2026