FDA 510(k) Premarket Notification

K181653 Ethicon Circular Stapler, Ethicon Circular Stapler -XL Sealed

CLEARED

Sep 18, 2018
88 days to decision

K181653 · Product code: **GDW** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k181653/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Implantable (GDW)
Date received	Jun 22, 2018
Decision date	Sep 18, 2018
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ethicon Endo-Surgery, LLC**
Location	Blue Ash, OH, US
Contact	Sigfrido Delgado
Website	https://www.jnjmedtech.com
510(k) history	69 submissions · 69 cleared · 2006-2026