FDA 510(k) Premarket Notification

K202593 Turbett Instrument Pod

CLEARED

May 19, 2021
253 days to decision

K202593 · Product code: **FRG** · General Hospital
Source: https://www.510kdatabase.net/k202593/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Sep 8, 2020
Decision date	May 19, 2021
Days to decision	253 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Turbett Surgical, Inc.**
Location	Rochester, NY, US
Contact	Rob Turbett
510(k) history	2 submissions · 2 cleared · 2020-2021

REGULATORY CONSULTANT

Consulting firm	**Fdc Services**
Contact	David Furr

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k202593/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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