FDA 510(k) Premarket Notification

K213252 Dornier Thulio

CLEARED

Jul 27, 2022
300 days to decision

K213252 · Product code: **GEX** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k213252/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 30, 2021
Decision date	Jul 27, 2022
Days to decision	300 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Dornier Medtech America, Inc.**
Location	Marietta, GA, US
Contact	John Hoffer
510(k) history	40 submissions · 40 cleared · 1990-2023