

**K213252 Dornier Thulio**Jul 27, 2022  
300 days to decisionK213252 · Product code: **GEX** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k213252/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213252/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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