

K221898 Gastrointestinal Boundary Identifier (GIBI HD)Jul 28, 2022
28 days to decisionK221898 · Product code: **KNT** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k221898/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Tubes, Gastrointestinal (and Accessories) (KNT)
Date received	Jun 30, 2022
Decision date	Jul 28, 2022
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Reshape Lifesciences
Location	San Clemente, CA, US
Contact	Michelle Ravert
510(k) history	4 submissions · 4 cleared · 2022-2024

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