

K242901 ZZIREN™ Orogastric TubeJan 10, 2025
109 days to decisionK242901 · Product code: **KNT** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k242901/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubes, Gastrointestinal (and Accessories) (KNT)
Date received	Sep 23, 2024
Decision date	Jan 10, 2025
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	ZZIREN™ SGT Orogastric Tube - 32 Fr (ZZ-SGT-32); ZZIREN™ SGT Orogastric Tube - 36 Fr (ZZ-SGT-36); ZZIREN™ SGT Orogastric Tube - 40 Fr (ZZ-SGT-40); ZZIREN™ GBT Orogastric Tube - 32 Fr (ZZ-GBT-32); ZZIREN™ GBT Orogastric Tube - 36 Fr (ZZ-GBT-36); ZZIREN™ GBT Orogastric Tube - 40 Fr (ZZ-GBT-40)

APPLICANT

Company	Tools For Surgery, LLC
Location	Stony Brook, NY, US
Contact	Arnold Leiboff
510(k) history	4 submissions · 4 cleared · 2004-2025

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