

K233591 StylusMay 31, 2024
205 days to decisionK233591 · Product code: **KNT** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k233591/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubes, Gastrointestinal (and Accessories) (KNT)
Date received	Nov 8, 2023
Decision date	May 31, 2024
Days to decision	205 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Degania Silicone , Ltd.
Location	Emek Hayarden, IL
Contact	Tali Raz
510(k) history	19 submissions · 17 cleared · 1988-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233591/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026