

K223916 PUMA-G SystemMar 29, 2023
90 days to decisionK223916 · Product code: **KGC** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k223916/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Gastro-enterostomy (KGC)
Date received	Dec 29, 2022
Decision date	Mar 29, 2023
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Coaptech, Inc.
Location	Baltimore, MD, US
Contact	Jack Kent
510(k) history	2 submissions · 2 cleared · 2023-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223916/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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