FDA 510(k) Premarket Notification

K232544 Apollo ESG NXT System, Apollo REVISE NXT System

CLEARED

Sep 18, 2023
27 days to decision

K232544 · Product code: **QTD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k232544/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endoscopic Suturing Device For Altering Gastric Anatomy For Weight Loss (QTD)
Date received	Aug 22, 2023
Decision date	Sep 18, 2023
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Apollo Endosurgery, Inc.**
Location	Austin, TX, US
Contact	James Shene
510(k) history	12 submissions · 10 cleared · 2008-2023

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k232544/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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