

K191784 Gabriel Feeding Tube with Balloon, and EnFit ConnectorNov 15, 2019
135 days to decisionK191784 · Product code: **PIF** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k191784/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - KD
Submission type	Traditional
Device classification	Gastrointestinal Tubes With Enteral Specific Connectors (PIF)
Date received	Jul 3, 2019
Decision date	Nov 15, 2019
Days to decision	135 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Syncro Medical Innovations, Inc.
Location	Macon, GA, US
Contact	Sabry Gabriel
510(k) history	6 submissions · 3 cleared · 2002-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191784/> 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 June 18, 2026