FDA 510(k) Premarket Notification

CLEARED

K171347 Bi-Funnel and Tri-Funnel Gastrostomy Feeding Tubes with ENFit Connection, Entuit Gastrostomy BR Balloon Retention Feeding Tube with ENFit Connection

Jun 6, 2017
29 days to decision

K171347 · Product code: **PIF** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k171347/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Gastrointestinal Tubes With Enteral Specific Connectors (PIF)
Date received	May 8, 2017
Decision date	Jun 6, 2017
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Xeridiem Medical Devices**
Location	Tucson, AZ, US
Contact	Steve Murray
510(k) history	3 submissions · 3 cleared · 2013-2017

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k171347/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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