FDA 510(k) Premarket Notification

CLEARED

K083684 ENDO VIVE STANDARD REPLACEMENT GASTROSTOMY TUBE, MODEL 82XX

Feb 5, 2009
55 days to decision

K083684 · Product code: **KNT** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k083684/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubes, Gastrointestinal (and Accessories) (KNT)
Date received	Dec 12, 2008
Decision date	Feb 5, 2009
Days to decision	55 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Manufacturing & Research, Inc.**
Location	Palm Harbor, FL, US
Contact	SUZANNE DEW
510(k) history	2 submissions · 2 cleared · 1995-2009