FDA 510(k) Premarket Notification

K955181 U.S. ENDOSCOPY GROUP, INC. BALLOON REPLACEMENT GASTROSTOMY TUBE

CLEARED

Jun 5, 1996
205 days to decision

K955181 · Product code: **KNT** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k955181/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubes, Gastrointestinal (and Accessories) (KNT)
Date received	Nov 13, 1995
Decision date	Jun 5, 1996
Days to decision	205 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**United States Endoscopy Group, Inc.**
Location	Mentor, OH, US
Contact	GRETCHEN YOUNKER
510(k) history	94 submissions · 92 cleared · 1991-2020