FDA 510(k) Premarket Notification

CLEARED

K131052 TUBECLEAR MODEL 101 (WITH NEW CLEARING STEM NE AND G MODELS)

Aug 16, 2013
123 days to decision

K131052 · Product code: **KNT** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k131052/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubes, Gastrointestinal (and Accessories) (KNT)
Date received	Apr 15, 2013
Decision date	Aug 16, 2013
Days to decision	123 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Actuated Medical, Inc.**
Location	Bellefonte, PA, US
Contact	DEBORA DEMERS, PH.D.
510(k) history	10 submissions · 10 cleared · 2012-2025