FDA 510(k) Premarket Notification

CLEARED

K091417 SINGLE USE GUIDEWIRE, MODELS G-240-2527S, G-240-2545S, G-240-2527A, G-240-2545A, G-240-3527S, G-240-3545S & G-240-3527A

May 22, 2009
9 days to decision

K091417 · Product code: **OCY** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k091417/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Guidewire, Gastroenterology-urology (OCY)
Date received	May 13, 2009
Decision date	May 22, 2009
Days to decision	9 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Terumo Corp.**
Location	Somerset, NJ, US
Contact	MARK UNTERREINER
510(k) history	21 submissions · 21 cleared · 1991-2010