FDA 510(k) Premarket Notification

K103456 THE SENSITITRE AIM

CLEARED

Jun 22, 2011
210 days to decision

K103456 · Product code: **LIE** · Microbiology
Source: https://www.510kdatabase.net/k103456/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent/device, Inoculum Calibration (LIE)
Date received	Nov 24, 2010
Decision date	Jun 22, 2011
Days to decision	210 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Trek Diagnostic Systems**
Location	Cleveland, OH, US
Contact	CYNTHIA C KNAPP
510(k) history	5 submissions · 5 cleared · 2011-2014