CLEARED

K121399 LUMINEX FLEXMAP 3D INSTRUMENT SYSTEM, LUMINEX XPONENT 4.0 SPI SOFTWARE, FLEXMAP 3D IVD CALIBRATION KIT, FLEXMAP 3D IVD P

Jan 9, 2013
245 days to decision

K121399 · Product code: **NSU** · Immunology
Source: https://www.510kdatabase.net/k121399/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrumentation For Clinical Multiplex Test Systems (NSU)
Date received	May 9, 2012
Decision date	Jan 9, 2013
Days to decision	245 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Luminex Corp.**
Location	Toronto, CA
Contact	Oliver Meek
510(k) history	3 submissions · 3 cleared · 2008-2014