

K131489 TRACTUS TISSUEMAPPER IMAGE RECORDING SYSTEM APPLICATION

Jun 25, 2013
33 days to decision

K131489 · Product code: IYO · Radiology
Source: <https://www.510kdatabase.net/k131489/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	May 23, 2013
Decision date	Jun 25, 2013
Days to decision	33 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Tractus Corporation
Location	Danville, CA, US
Contact	MARK JOB
510(k) history	2 submissions · 2 cleared · 2013-2013

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k131489/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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