

K152126 UST-5550-RAug 17, 2016
383 days to decisionK152126 · Product code: **ITX** · Radiology
Source: <https://www.510kdatabase.net/k152126/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Jul 31, 2015
Decision date	Aug 17, 2016
Days to decision	383 days
Third-party review	No
Summary / Statement	Summary
Other names	UST-5536-R; L43K

APPLICANT

Company	Hitachi Aloka Medical America, Inc.
Location	Wallingford, CT, US
Contact	ANGELA VAN ARSDALE
510(k) history	3 submissions · 3 cleared · 2014-2016

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