

K150342 Touch UltrasoundMay 8, 2015
86 days to decisionK150342 · Product code: **IYO** · Radiology
Source: <https://www.510kdatabase.net/k150342/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Feb 11, 2015
Decision date	May 8, 2015
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Carestream Health, Inc.
Location	Rochester, NY, US
Contact	CAROLYN L WAGNER
Website	http://www.carestream.com/default.aspx?LangType=1033
510(k) history	48 submissions · 48 cleared · 2008-2025

Carestream Health, Inc. is a worldwide provider of medical imaging systems and X-ray imaging solutions. The company operates with a manufacturing facility in Rochester, US and maintains a global service and support network across multiple markets. Carestream has received FDA 510(k) clearances from total submissions since 2008. The company specializes in Radiology devices, which represent 94% of its regulatory submissions. The latest clearance was granted in 2025, demonstrating continued active development and market engagement. Recent cleared devices include digital radio...
