

K152467 Touch UltrasoundDec 9, 2015
100 days to decisionK152467 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k152467/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Aug 31, 2015
Decision date	Dec 9, 2015
Days to decision	100 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...
