

K170338 A-ViewMay 16, 2017
103 days to decisionK170338 · Product code: **ITX** · Radiology
Source: <https://www.510kdatabase.net/k170338/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Feb 2, 2017
Decision date	May 16, 2017
Days to decision	103 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Stroke2prevent B.V.
Location	8025 Az Zwolle, NL
Contact	Maarten Nibbelke
510(k) history	1 submissions · 1 cleared · 2017-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k170338/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 16, 2026