

K151027 zensor systemOct 2, 2015
168 days to decisionK151027 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k151027/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Apr 17, 2015
Decision date	Oct 2, 2015
Days to decision	168 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Intelesens Limited
Location	Bonita Springs, FL, US
Contact	PATRICIA PEPPER
510(k) history	3 submissions · 3 cleared · 2011-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k151027/> 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 June 3, 2026