

K190955 Hypotension Decision AssistNov 27, 2019
230 days to decisionK190955 · Product code: **DXG** · Cardiovascular
Source: <https://www.510kdatabase.net/k190955/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Pre-programmed, Single-function (DXG)
Date received	Apr 11, 2019
Decision date	Nov 27, 2019
Days to decision	230 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Directed Systems, Ltd.
Location	Cambridge, GB
Contact	Mark S. Leaning
510(k) history	2 submissions · 2 cleared · 2019-2021

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