

K132892 TEBCO-WAug 1, 2014
319 days to decisionK132892 · Product code: **DXG** · Cardiovascular
Source: <https://www.510kdatabase.net/k132892/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Pre-programmed, Single-function (DXG)
Date received	Sep 16, 2013
Decision date	Aug 1, 2014
Days to decision	319 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bomed, Inc.
Location	Kamuela, HI, US
Contact	B. BO SRAMEK, PH.D
510(k) history	1 submissions · 1 cleared · 2014-2014

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