

K113007 BIONIME DIABETES MANAGEMENT SYSTEM VI.0Feb 27, 2012
143 days to decisionK113007 · Product code: **JQP** · Chemistry
Source: <https://www.510kdatabase.net/k113007/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calculator/data Processing Module, For Clinical Use (JQP)
Date received	Oct 7, 2011
Decision date	Feb 27, 2012
Days to decision	143 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bionime Corporation
Location	Great Neck, NY, US
Contact	Feng-Yu Lee
510(k) history	21 submissions · 21 cleared · 2005-2024

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