

K031647 BIOSIGN SSI BIOLOGICAL TEST PACK WITH INSTANT READOUT INTEGRATORJul 29, 2003
63 days to decisionK031647 · Product code: JOJ · General Hospital
Source: <https://www.510kdatabase.net/k031647/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator, Physical/chemical Sterilization Process (JOJ)
Date received	May 27, 2003
Decision date	Jul 29, 2003
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Getinge USA, Inc.
Location	Rochester, NY, US
Contact	KARLA BYRNE
510(k) history	4 submissions · 4 cleared · 2003-2005

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