

**K053011 PRO-NEO NEONATAL ECG ELECTRODE, MODELS
SG15 AND SR20**Dec 14, 2005
49 days to decisionK053011 · Product code: **DRX** · Cardiovascular
Source: <https://www.510kdatabase.net/k053011/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrocardiograph (DRX)
Date received	Oct 26, 2005
Decision date	Dec 14, 2005
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bio Protech, Inc.
Location	Sparks, NV, US
Contact	E.J. Smith
510(k) history	17 submissions · 17 cleared · 2002-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k053011/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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