

**K003804 SENSI-PREMA NEONATAL ECG ELECTRODES, 40612,
40614,40626,40550,40554,40555,440556,40610,40613,40625,4080
1**Aug 30, 2001
265 days to decisionK003804 · Product code: **DRX** · Cardiovascular
Source: <https://www.510kdatabase.net/k003804/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Electrode, Electrocardiograph (DRX)
Date received	Dec 8, 2000
Decision date	Aug 30, 2001
Days to decision	265 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Niko Medical Products
Location	Fort Worth, TX, US
Contact	RICHARD A HAMER
510(k) history	1 submissions · 1 cleared · 2001-2001

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