

K081388 GLUCOCARE INTENSIVE GLYCEMIC CONTROL SYSTEMAug 21, 2008
94 days to decisionK081388 · Product code: **NDC** · General Hospital
Source: <https://www.510kdatabase.net/k081388/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calculator, Drug Dose (NDC)
Date received	May 19, 2008
Decision date	Aug 21, 2008
Days to decision	94 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pronia Medical System, LLC
Location	North Attleboro, MA, US
Contact	CYNTHIA J.M. NOLTE
510(k) history	1 submissions · 1 cleared · 2008-2008

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081388/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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