

K103278 ACURA PLUS BLOOD GLUCOSE MONITORING SYSTEMOct 28, 2011
357 days to decisionK103278 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k103278/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Nov 5, 2010
Decision date	Oct 28, 2011
Days to decision	357 days
Third-party review	No
Summary / Statement	Summary
Other names	ACURA PLUS BLOOD GLUCOSE METER; ACURA CONTROL SOLUTION

APPLICANT

Company	I-Sens, Inc.
Location	Seoul, KR
Contact	HYUN JOON OH
510(k) history	27 submissions · 27 cleared · 2008-2023

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