

**K992148 HYDRAGEL-MINI ISO-CK KIT, HYDRAGEL ISO-CK KIT,
HYDRAGEL 7 ISO-CK KIT, HYDRAGEL ISO-CK 15/30 KIT**

Dec 29, 1999
188 days to decision

K992148 · Product code: **CGS** · Chemistry
Source: <https://www.510kdatabase.net/k992148/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nad Reduction/nadh Oxidation, Cpk Or Isoenzymes (CGS)
Date received	Jun 24, 1999
Decision date	Dec 29, 1999
Days to decision	188 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Morax
Location	Chelsea, MI, US
Contact	BOREK JANIK
510(k) history	12 submissions · 12 cleared · 1996-2003

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k992148/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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