FDA 510(k) Premarket Notification

K060280 ICHEM 100 URINE CHEMISTRY ANALYZER

CLEARED

Jun 13, 2006
131 days to decision

K060280 · Product code: **JIL** · Chemistry
Source: https://www.510kdatabase.net/k060280/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Method, Enzymatic, Glucose (urinary, Non-quantitative) (JIL)
Date received	Feb 2, 2006
Decision date	Jun 13, 2006
Days to decision	131 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Iris International, Inc.**
Location	Chatsworth, CA, US
Contact	GERALD J HADDOCK
Website	http://www.proiris.com/
510(k) history	3 submissions · 3 cleared · 2005-2010

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k060280/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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