

K030528 ATAC IRON REAGENT, ATAC TIBC COLUMN KIT AND IRON CALIBRATOR (500 UG/DL)

Jun 17, 2003
118 days to decision

K030528 · Product code: JIY · Chemistry
Source: <https://www.510kdatabase.net/k030528/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Photometric Method, Iron (non-heme) (JIY)
Date received	Feb 19, 2003
Decision date	Jun 17, 2003
Days to decision	118 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Clinical Data
Location	Brea, CA, US
Contact	WYNN STOCKING
510(k) history	1 submissions · 1 cleared · 2003-2003

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k030528/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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