FDA 510(k) Premarket Notification

K050869 MODIFICATION TO ABL800 FLEX

CLEARED

Aug 11, 2005
127 days to decision

K050869 · Product code: **CIG** · Chemistry
Source: https://www.510kdatabase.net/k050869/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Apr 6, 2005
Decision date	Aug 11, 2005
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Radiometer Medical Aps**
Location	Bronshoj, DK
Contact	MARK A HELLER
510(k) history	28 submissions · 28 cleared · 2004-2017

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k050869/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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