FDA 510(k) Premarket Notification

K081360 PATHFAST CK-MB-II, PATHFAST MYO-II

CLEARED

Aug 17, 2009
459 days to decision

K081360 · Product code: **JHX** · Chemistry
Source: https://www.510kdatabase.net/k081360/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorometric Method, Cpk Or Isoenzymes (JHX)
Date received	May 15, 2008
Decision date	Aug 17, 2009
Days to decision	459 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Mitsubishi Kagaku Iatron**
Location	Seattle, WA, US
Contact	HELEN LANDICHO
510(k) history	4 submissions · 4 cleared · 2008-2009