

**K060359 ARCHIECT INSULIN AND CONTROLS, MODEL
8K41-01, 8K41-10**

Apr 14, 2006
60 days to decision

K060359 · Product code: **JIT** · Chemistry
Source: <https://www.510kdatabase.net/k060359/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Calibrator, Secondary (JIT)
Date received	Feb 13, 2006
Decision date	Apr 14, 2006
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Denka Seiken Co., Ltd.
Location	Gosen City, Niigata, JP
Contact	TOSHIMI MATSUNAGA
510(k) history	6 submissions · 6 cleared · 2003-2017

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k060359/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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