FDA 510(k) Premarket Notification

K063146 ACCU-CHEK LINKASSIST

CLEARED

Nov 27, 2006
42 days to decision

K063146 · Product code: **KZH** · General Hospital
Source: https://www.510kdatabase.net/k063146/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Syringe Needle (KZH)
Date received	Oct 16, 2006
Decision date	Nov 27, 2006
Days to decision	42 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Disetronic Medical Systems AG**
Location	Fort Myers, FL, US
Contact	Scott Thiel
510(k) history	12 submissions · 12 cleared · 2000-2010