

K953452 KETOREX C SANWAMay 2, 1996
289 days to decisionK953452 · Product code: **JMK** · Chemistry
Source: <https://www.510kdatabase.net/k953452/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Acid, Alpha-ketobutyric And Nadh (u.v.), Hydroxybutyric Dehydrogenase (JMK)
Date received	Jul 18, 1995
Decision date	May 2, 1996
Days to decision	289 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Ihara Medics U.S., Inc.
Location	Valencia, CA, US
Contact	LEONARD SPOLTER
510(k) history	5 submissions · 5 cleared · 1990-1996

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