

K885263 QMS(TM) - THEOPHYLLINEMar 28, 1989
95 days to decisionK885263 · Product code: **JQX** · Chemistry
Source: <https://www.510kdatabase.net/k885263/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nephelometer, For Clinical Use (JQX)
Date received	Dec 23, 1988
Decision date	Mar 28, 1989
Days to decision	95 days
Third-party review	No

APPLICANT

Company	Seradyn, Inc.
Location	Indianapolis, IN, US
Contact	J SULLIVAN
510(k) history	28 submissions · 28 cleared · 1988-2007

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k885263/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026