

K860413 BIOTIS TSIFeb 24, 1986
21 days to decisionK860413 · Product code: **JSE** · Microbiology
Source: <https://www.510kdatabase.net/k860413/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Culture Media, Multiple Biochemical Test (JSE)
Date received	Feb 3, 1986
Decision date	Feb 24, 1986
Days to decision	21 days
Third-party review	No

APPLICANT

Company	Otisville Biotech, Inc.
Location	Walker, MI, US
Contact	ERNEST M GREEN
510(k) history	98 submissions · 98 cleared · 1983-1986

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k860413/>; 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 July 1, 2026