

K970830 REMEL LEVOFLOXACIN 5G SUSCEPTIBILITY DISKApr 2, 1997
26 days to decisionK970830 · Product code: **JTN** · Microbiology
Source: <https://www.510kdatabase.net/k970830/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Susceptibility Test Discs, Antimicrobial (JTN)
Date received	Mar 7, 1997
Decision date	Apr 2, 1997
Days to decision	26 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Remel, Inc.
Location	Lenexa, KS, US
Contact	MARY A SILVIUS
510(k) history	17 submissions · 17 cleared · 1994-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k970830/> 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 1, 2026