

K912613 GENTAMICIN 500 UG/ML TO BE INCLUDED IN JUSTONE(TM)

Aug 22, 1991
71 days to decision

K912613 · Product code: **JWY** · Microbiology
Source: <https://www.510kdatabase.net/k912613/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Jun 12, 1991
Decision date	Aug 22, 1991
Days to decision	71 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Sensititre Microbiology A Div. of Radiometer
Location	Westlake, OH, US
Contact	KATHLEEN M ONTKO
510(k) history	3 submissions · 3 cleared · 1991-1992

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k912613/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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