

**K964009 IMAGE IMMUNOCHEMISTRY SYSTEM
GENTAMICIN(GEN)/TOBRAMYCIN(TOB) REAGENT / BECKMAN
DRUG CLAIBRATOR 3 PLUS**Feb 11, 1997
127 days to decisionK964009 · Product code: **DNO** · Toxicology
Source: <https://www.510kdatabase.net/k964009/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemagglutination Inhibition, Gentamicin (DNO)
Date received	Oct 7, 1996
Decision date	Feb 11, 1997
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Beckman Instruments, Inc.
Location	Mchenry, IL, US
Contact	ANNETTE HELLIE
Website	https://www.beckman.com
510(k) history	281 submissions · 281 cleared · 1976-1998

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