

**K885003 BACTIGEN(R) GROUP B STREPTOCOCCUS TEST**Feb 7, 1989  
68 days to decisionK885003 · Product code: **GTZ** · Microbiology  
Source: <https://www.510kdatabase.net/k885003/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, All Groups, Streptococcus Spp. (GTZ)
Date received	Dec 1, 1988
Decision date	Feb 7, 1989
Days to decision	68 days
Third-party review	No

**APPLICANT**

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Company	<b>Armkel, LLC</b>
Location	Mchenry, IL, US
Contact	ANN MACLEARIE
510(k) history	68 submissions · 68 cleared · 1979-2004

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