

K070310 B R A H M S PCT SENSITIVE KRYPTOR TEST SYSTEM

Mar 31, 2008
424 days to decision

K070310 · Product code: **NTM** · Microbiology
Source: <https://www.510kdatabase.net/k070310/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Inflammatory Response Marker, Sepsis (NTM)
Date received	Feb 1, 2007
Decision date	Mar 31, 2008
Days to decision	424 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Brahms Aktiengesellschaft
Location	Beltsville, MD, US
Contact	JONAS LEICHTNER
510(k) history	2 submissions · 2 cleared · 2005-2008

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Device record: <https://www.510kdatabase.net/k070310/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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