

**K904416 CROATEST (R) RHEUMATOID DIAGNOSTIC**Jun 24, 1991  
270 days to decisionK904416 · Product code: **GTQ** · Microbiology  
Source: <https://www.510kdatabase.net/k904416/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antistreptolysin - Titer/streptolysin O Reagent (GTQ)
Date received	Sep 27, 1990
Decision date	Jun 24, 1991
Days to decision	270 days
Third-party review	No

**APPLICANT**

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Company	<b>Biotrax, Inc.</b>
Location	Baltimore, MD, US
Contact	SANTO L GRILLO
510(k) history	4 submissions · 4 cleared · 1990-1991

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k904416/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 30, 2026