

**K812078 GONOZYME (10 COPIES FRWD. W/ORIG. TO BG)**

Jul 23, 1981

K812078 · Product code: JTY · Microbiology  
Source: <https://www.510kdatabase.net/k812078/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - SP
Submission type	Traditional
Device classification	Culture Media, For Isolation Of Pathogenic Neisseria (JTY)
Date received	Jul 23, 1981
Decision date	Jul 23, 1981
Third-party review	No

**APPLICANT**

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Company	<b>Abbott Laboratories</b>
Location	Abbott Park, IL, US
Website	<a href="http://www.abbott.com">http://www.abbott.com</a>
510(k) history	883 submissions · 868 cleared · 1976-2026

Abbott Laboratories is an American multinational medical devices and health care company headquartered in Abbott Park, Illinois. The company operates in over 160 countries and produces pharmaceuticals, diagnostics, nutritional products, and medical devices. Abbott maintains a substantial FDA 510(k) regulatory record with FDA 510(k) cleared devices from total submissions since 1976. The company's cleared devices span chemistry, microbiology, hematology, immunology, and toxicology categories. The latest clearance in 2025 reflects continued regulatory activity and product de...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k812078/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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