

K063224 GENTRISURE HUMAN GENOMIC DNA REFERENCE CONTROL

Dec 22, 2006
59 days to decision

K063224 · Product code: **NZB** · Chemistry
Source: <https://www.510kdatabase.net/k063224/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Quality Control Material, Genetics, Dna (NZB)
Date received	Oct 24, 2006
Decision date	Dec 22, 2006
Days to decision	59 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Gentris Corporation
Location	Morrisville, NC, US
Contact	DEBORAH N KLOOS
510(k) history	1 submissions · 1 cleared · 2006-2006

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k063224/> Data sourced from FDA 510(k) public records (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. - Generated June 29, 2026