FDA 510(k) Premarket Notification

K063224 GENTRISURE HUMAN GENOMIC DNA REFERENCE CONTROL

CLEARED

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