FDA 510(k) Premarket Notification

K931756 QUANTIKINE(TM) ERYTHROPOIETIN HUMAN SERUM CONTROLS

CLEARED

Apr 21, 1994
378 days to decision

K931756 · Product code: **GGT** · Hematology
Source: https://www.510kdatabase.net/k931756/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Erythropoietin (GGT)
Date received	Apr 8, 1993
Decision date	Apr 21, 1994
Days to decision	378 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**R&D Systems, Inc.**
Location	Mchenry, IL, US
Contact	KARYN STEERE
510(k) history	79 submissions · 79 cleared · 1978-2016