FDA 510(k) Premarket Notification

K893562 A.QC HCT LEVEL 1 AND 2

CLEARED

Jul 14, 1989
66 days to decision

K893562 · Product code: **GLK** · Hematology
Source: https://www.510kdatabase.net/k893562/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Control, Hematocrit (GLK)
Date received	May 9, 1989
Decision date	Jul 14, 1989
Days to decision	66 days
Third-party review	No

APPLICANT

Company	**Johnson & Johnson Professionals, Inc.**
Location	Raynham, MA, US
Contact	PETER J CORDON
Website	https://www.jnj.com
510(k) history	206 submissions · 184 cleared · 1976-2000

Johnson & Johnson Professionals, Inc. is a medical device company based in Raynham, Massachusetts. The company specializes in surgical and orthopedic devices. The company has received FDA 510(k) clearances from total submissions between 1976 and 2000. Orthopedic devices and neurosurgical instruments represent core product categories. Notable cleared devices include hip and elbow prostheses, programmable valve systems, and aneurysm clips. The company is inactive and represents a historical regulatory record with no submissions in more than two decades. Explore the complete...