FDA 510(k) Premarket Notification

K833636 ORTHO* SERUM ELISA TEST SYSTEM

CLEARED

Jun 13, 1984
240 days to decision

K833636 · Product code: **DAK** · Immunology
Source: https://www.510kdatabase.net/k833636/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Complement C1q, Antigen, Antiserum, Control (DAK)
Date received	Oct 17, 1983
Decision date	Jun 13, 1984
Days to decision	240 days
Third-party review	No

APPLICANT

Company	**Ortho Diagnostic Systems, Inc.**
Location	Carpinteria, CA, US
510(k) history	126 submissions · 126 cleared · 1981-1997

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k833636/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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