FDA 510(k) Premarket Notification

K874180 COLORECTAL CANCER RISK DETECTOR (TM)

CLEARED

Sep 30, 1988
352 days to decision

K874180 · Product code: **KHE** · Hematology
Source: https://www.510kdatabase.net/k874180/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Occult Blood (KHE)
Date received	Oct 14, 1987
Decision date	Sep 30, 1988
Days to decision	352 days
Third-party review	No

APPLICANT

Company	**Pearce Clinical Laboratories, Inc.**
Location	Conroe, TX, US
Contact	PEARCE, PHD
510(k) history	3 submissions · 3 cleared · 1987-1988

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k874180/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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