FDA 510(k) Premarket Notification

K832396 CENTRAL VENOUS ACCESS CATHETER CVAC

CLEARED

Aug 31, 1983
42 days to decision

K832396 · Product code: **DOY** · Toxicology
Source: https://www.510kdatabase.net/k832396/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Digoxin (3-h), Goat Antibody, 2nd Antibody Sep. (DOY)
Date received	Jul 20, 1983
Decision date	Aug 31, 1983
Days to decision	42 days
Third-party review	No

APPLICANT

Company	**Gish Biomedical, Inc.**
Location	Mchenry, IL, US
510(k) history	75 submissions · 75 cleared · 1983-2009

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k832396/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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