FDA 510(k) Premarket Notification

K910685 WEHRS INCUS AND INCUS-STAPES PROSTHESES

CLEARED

Dec 4, 1991
288 days to decision

K910685 · Product code: **ETB** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k910685/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Partial Ossicular Replacement (ETB)
Date received	Feb 19, 1991
Decision date	Dec 4, 1991
Days to decision	288 days
Third-party review	No

APPLICANT

Company	**Smith & Nephew Richards, Inc.**
Location	Memphus, TN, US
Contact	ROBERT F GAMES
510(k) history	87 submissions · 72 cleared · 1990-1997

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k910685/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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