FDA 510(k) Premarket Notification

K905757 AIA-PACK HGH

CLEARED

Jan 25, 1991
29 days to decision

K905757 · Product code: **CFL** · Chemistry
Source: https://www.510kdatabase.net/k905757/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Human Growth Hormone (CFL)
Date received	Dec 27, 1990
Decision date	Jan 25, 1991
Days to decision	29 days
Third-party review	No

APPLICANT

Company	**Tosoh Medics, Inc.**
Location	Washington, DC, US
Contact	HOWARD M HOLSTEIN
510(k) history	41 submissions · 41 cleared · 1990-2002

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k905757/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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