

K003916 DERMALIFE HYDROFUSION SKIN & BODY CARE SYSTEM

Apr 15, 2002
482 days to decision

K003916 · Product code: **IMB** · Physical Medicine
Source: <https://www.510kdatabase.net/k003916/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cabinet, Moist Steam (IMB)
Date received	Dec 19, 2000
Decision date	Apr 15, 2002
Days to decision	482 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Scandia Manufacturing , Ltd.
Location	Bloomington, MN, US
Contact	RONALD E BERGLUND
510(k) history	1 submissions · 1 cleared · 2002-2002

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Device record: <https://www.510kdatabase.net/k003916/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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