FDA 510(k) Premarket Notification

K810200 OPTIPORE SCRUB SPONGE

CLEARED

Feb 13, 1981
21 days to decision

K810200 · Product code: **EFQ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k810200/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gauze/sponge, Internal (EFQ)
Date received	Jan 23, 1981
Decision date	Feb 13, 1981
Days to decision	21 days
Third-party review	No

APPLICANT

Company	**Bio Syntec**
Location	Walker, MI, US
510(k) history	1 submissions · 1 cleared · 1981-1981

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k810200/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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