

K032282 MODIFICATION TO HEDROCEL TRABECULAR METAL RECONSTRUCTION SYSTEM

Aug 21, 2003
28 days to decision

K032282 · Product code: **EZX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k032282/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Metal (EZX)
Date received	Jul 24, 2003
Decision date	Aug 21, 2003
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Implex Corp.
Location	Allendale, NJ, US
Contact	MARCI HALEVI
510(k) history	65 submissions · 61 cleared · 1993-2005

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k032282/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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