

**K032344 THE HEDROCEL TRABECULAR METAL RECONSTRUCTION SYSTEM MODEL 10-330**

Oct 2, 2003  
64 days to decision

K032344 · Product code: **EZX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k032344/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Metal (EZ)
Date received	Jul 30, 2003
Decision date	Oct 2, 2003
Days to decision	64 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k032344/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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