

K963899 CAUSSE UNIVERSAL OSSICULAR REPLACEMENT PROSTHESIS (ORP/1)

Aug 22, 1997
329 days to decision

K963899 · Product code: **ETA** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k963899/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Replacement, Ossicular Prosthesis, Total (ETA)
Date received	Sep 27, 1996
Decision date	Aug 22, 1997
Days to decision	329 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Exmoor Plastics , Ltd.
Location	Walker, MI, US
Contact	BRIAN EAST
510(k) history	43 submissions · 43 cleared · 1981-2010

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Device record: <https://www.510kdatabase.net/k963899/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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