

K981045 EXMOOR TEFLON LOOP REPLACEMENT PROSTHESISMay 20, 1998
61 days to decisionK981045 · Product code: **ETB** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k981045/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Partial Ossicular Replacement (ETB)
Date received	Mar 20, 1998
Decision date	May 20, 1998
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k981045/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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