

**K911613 VAR AURAL GROM AG/S9,SD8.00.28.5/0.2 NS/S/6823  
1.4**Jun 28, 1991  
86 days to decisionK911613 · Product code: **LCR** · Toxicology  
Source: <https://www.510kdatabase.net/k911613/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescent Immunoassay, Tobramycin (LCR)
Date received	Apr 3, 1991
Decision date	Jun 28, 1991
Days to decision	86 days
Third-party review	No

**APPLICANT**

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

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k911613/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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