

**K896098 GUARDIAN & JANITEX CONDOM/PROPHYLACTIC**Dec 19, 1990  
425 days to decisionK896098 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k896098/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Oct 20, 1989
Decision date	Dec 19, 1990
Days to decision	425 days
Third-party review	No

**APPLICANT**

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Company	<b>Allied Rubber Industries Sdn. Bhd.</b>
Location	400000 Shah Alam.Malaysia, MY
Contact	TONG
510(k) history	2 submissions · 2 cleared · 1989-1990

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k896098/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 30, 2026