

**K040396 ULTRASONIC SCALER ELEGANCE MS-10 (25K)**Apr 22, 2004  
65 days to decisionK040396 · Product code: **ELC** · Dental  
Source: <https://www.510kdatabase.net/k040396/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Scaler, Ultrasonic (ELC)
Date received	Feb 17, 2004
Decision date	Apr 22, 2004
Days to decision	65 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Rolence Enterprise, Inc.</b>
Location	Chungj, TW
Contact	STERLING CHENG
510(k) history	2 submissions · 2 cleared · 2004-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k040396/> 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 July 1, 2026