

**K201115 Next Generation Balloon Dilation System**Aug 27, 2020  
122 days to decisionK201115 · Product code: **LRC** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k201115/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Ent Manual Surgical (LRC)
Date received	Apr 27, 2020
Decision date	Aug 27, 2020
Days to decision	122 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Acclarent, Inc.</b>
Location	Irvine, CA, US
Contact	David Locke
Website	<a href="https://www.acclarent.com">https://www.acclarent.com</a>
510(k) history	45 submissions · 44 cleared · 2005-2026

Acclarent, Inc. is a subsidiary of Integra LifeSciences based in Irvine, California. The company develops technology for Ear, Nose, Throat related conditions. Acclarent has received FDA 510(k) clearances from total submissions since its first clearance in 2005. Ear, Nose, Throat devices represent the dominant focus, accounting for 76% of all submissions. The company's latest clearance was in 2026, demonstrating continued regulatory activity. The company specializes in minimally invasive surgical instruments and balloon dilation systems for sinus and Eustachian tube proced...

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