

K171165 SmartByte DeviceMay 18, 2017
28 days to decisionK171165 · Product code: **ONY** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k171165/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oral Removable Retainer For Weight Management (ONY)
Date received	Apr 20, 2017
Decision date	May 18, 2017
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Scientific Intake
Location	Atlanta, GA, US
Contact	Marc Gibeley
510(k) history	2 submissions · 1 cleared · 2016-2017

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