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510(k) Premarket Notification



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Device Classification Name	Aligner, Sequential ²²
510(K) Number	K190003
Device Name	Vivid Aligners
Applicant	Orthodont Laboratory, Inc. 6325 Sheridan Drive Buffalo, NY 14221
Applicant Contact Correspondent	Michael Wright Compliance Systems International, LLC. 1083 Delaware Ave. Buffalo, NY 14209
Correspondent Contact	Robert O. Dean
Regulation Number	872.5470 ²³
Classification Product Code	NXC ²⁴
Date Received	01/02/2019
Decision Date	11/06/2019
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Dental
510k Review Panel	Dental
Summary	Summary ²⁵
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

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