510(k) Premarket Notification

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Device Classification Name	Aligner, Sequential[22]
510(K) Number	K190003
Device Name	Vivid Aligners
Applicant	Orthodent Laboratory, Inc. 6325 Sheridan Drive Buffalo, NY 14221
Applicant Contact	Michael Wright
Correspondent	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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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
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