Class 2 Device Recall Virtual XD

See Related Information 22

Date Initiated by Firm	November 09, 2016
Create Date	December 07, 2016
Recall Status[1]	Open[3], Classified
Recall Number	Z-0717-2017
Recall Event ID	75620[23]
510(K)Number	K083739[24]
Product Classification	Material, impression[25] - **Product Code** ELW[26]
Product	Virtual XD Refill Light Body Fast Set Wash Material, 2X50 ml, REF #/Product Code 646461, Rx ONLY -- product Usage: Dental impression material
Code Information	Lot No./Expiration Date: UL2395/June 28, 2018; UL2293/Dec 31, 2017; UL2222/Aug 28, 2017; UL2220/July 28, 2017; TL4121/ Mar 28, 2017.
Recalling Firm/ Manufacturer	Ivoclar Vivadent, Inc. 175 Pineview Dr Amherst NY 14228-2231
For Additional Information Contact	Ivoclar Vivadent Customer Service 800-533-6825
Manufacturer Reason for Recall	The firm received complaints claiming the dental material failed to set up. As the dental material ages, the set time may increase.
FDA Determined Cause [2]	Under Investigation by firm
Action	Ivoclar Vivadent sent and URGENT - MEDICAL DEVICE RECALL Letters (dated 11/07/2016) and Recall Response Forms to customers via Certified Mail-Return Receipt Requested. The letter identified the affected product, problem and actions to be taken. Customers were advised to return all affected products in stock. For questions contact Ivoclar Vivadent Customer Service at 800-533-6825.
Quantity in Commerce	US: 4659 units, Canada: 729 units
Distribution	Worldwide Distribution - US Nationwide and the countries of Canada and Australia
Total Product Life Cycle	TPLC Device Report[27]

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[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[28].

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

Class 2 Device Recall Virtual XD

See Related Information[22]

Date Initiated by Firm	November 09, 2016
Create Date	December 07, 2016
Recall Status[1]	Open[3], Classified
Recall Number	Z-0718-2017
Recall Event ID	75620[23]
510(K)Number	K083739[24]
Product Classification	Material, impression[25] - **Product Code** ELW[26]
Product	Virtual XD Refill Light Body Regular Set Wash Material, 2X50 ml, REF #/Product Code 646462, Rx ONLY -- Product Usage: Dental impression material
Code Information	Lot No./Expiration Date: UL2221/July 28, 2017; TL4056/Nov 28, 2016
Recalling Firm/ Manufacturer	Ivoclar Vivadent, Inc. 175 Pineview Dr Amherst NY 14228-2231
For Additional Information Contact	Ivoclar Vivadent Customer Service 800-533-6825
Manufacturer Reason for Recall	The firm received complaints claiming the dental material failed to set up. As the dental material ages, the set time may increase.
FDA Determined Cause [2]	Under Investigation by firm
Action	Ivoclar Vivadent sent and URGENT - MEDICAL DEVICE RECALL Letters (dated 11/07/2016) and Recall Response Forms to customers via Certified Mail-Return Receipt Requested. The letter identified the affected product, problem and actions to be taken. Customers were advised to return all affected products in stock. For questions contact Ivoclar Vivadent Customer Service at 800-533-6825.
Quantity in Commerce	US: 1867 units, Canada: 465 units
Distribution	Worldwide Distribution - US Nationwide and the countries of Canada and Australia
Total Product Life Cycle	TPLC Device Report[27]

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[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[28].

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

Class 2 Device Recall Virtual XD

See Related Information 22

Date Initiated by Firm	November 09, 2016
Create Date	December 07, 2016
Recall Status[1]	Open[3], Classified
Recall Number	Z-0719-2017
Recall Event ID	75620[23]
510(K)Number	K083739[24]
Product Classification	Material, impression[25] - **Product Code** ELW[26]
Product	Virtual XD Test Pack Heavy/Light Fast Set, 2 x 50 ml, REF #/Product Code 646469, Rx ONLY -- Product Usage: Dental impression material
Code Information	Lot No./Expiration Date: TL4095/Jan 15, 2017; TL4094/Jan 15, 2017
Recalling Firm/ Manufacturer	Ivoclar Vivadent, Inc. 175 Pineview Dr Amherst NY 14228-2231
For Additional Information Contact	Ivoclar Vivadent Customer Service 800-533-6825
Manufacturer Reason for Recall	The firm received complaints claiming the dental material failed to set up. As the dental material ages, the set time may increase.
FDA Determined Cause [2]	Under Investigation by firm
Action	Ivoclar Vivadent sent and URGENT - MEDICAL DEVICE RECALL Letters (dated 11/07/2016) and Recall Response Forms to customers via Certified Mail-Return Receipt Requested. The letter identified the affected product, problem and actions to be taken. Customers were advised to return all affected products in stock. For questions contact Ivoclar Vivadent Customer Service at 800-533-6825.
Quantity in Commerce	US: 2090 units, Canada: 331 units, Australia: 465 units
Distribution	Worldwide Distribution - US Nationwide and the countries of Canada and Australia
Total Product Life Cycle	TPLC Device Report[27]

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[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[28].

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.