Date Initiated by Firm: November 09, 2016
Create Date: December 07, 2016
Recall Status: Open, Classified
Recall Number: Z-0717-2017
Recall Event ID: 75620
510(K) Number: K083739
Product Classification: Material, impression - Product Code ELW
Product: Virtual XD Refill Light Body Fast Set Wash Material, 2X50 ml, REF #/Product Code 646461, Rx ONLY -- product Usage: Dental impression material
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: 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

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.
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

## Date Initiated by Firm
November 09, 2016

## Create Date
December 07, 2016

## Recall Status
Open, Classified

## Recall Number
Z-0718-2017

## Recall Event ID
75620

## 510(K)Number
K083739

## Product Classification
Material, impression - Product Code ELW

## 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
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

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<td>Product Classification</td>
<td>Material, impression - Product Code ELW</td>
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<tr>
<td>Product</td>
<td>Virtual XD Test Pack Heavy/Light Fast Set, 2 x 50 ml, REF #/Product Code 646469, Rx ONLY --</td>
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<td>Product Usage</td>
<td>Dental impression material</td>
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<td>Code Information</td>
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</tr>
<tr>
<td>Quantity in Commerce</td>
<td>US: 2090 units, Canada: 331 units, Australia: 465 units</td>
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<td>Distribution</td>
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</tr>
<tr>
<td>Total Product Life Cycle</td>
<td>TPLC Device Report</td>
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