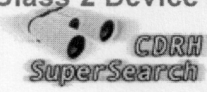


FDA Home<sup>3</sup> Medical Devices<sup>4</sup> Databases<sup>5</sup>

**Class 2 Device Recall Virtual XD**

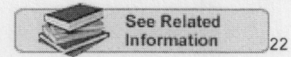


6 510(k)|DeNovo<sup>8</sup> | Registration & Listing<sup>9</sup> | Adverse Events<sup>10</sup> | Recalls<sup>11</sup>|PMA<sup>12</sup>|HDE<sup>13</sup>|Classification<sup>14</sup>|Standards<sup>15</sup>  
 CFR Title 21<sup>16</sup>|Radiation-Emitting Products<sup>17</sup>|X-Ray Assembler<sup>18</sup>|Medsun Reports<sup>19</sup>|CLIA<sup>20</sup>|TPLC<sup>21</sup>

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[Back to Search Results](#)

**Class 2 Device Recall Virtual XD**

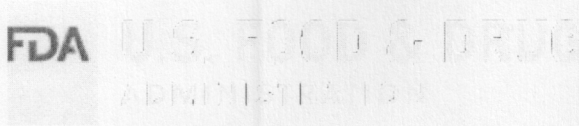


<b>Date Initiated by Firm</b>	November 09, 2016
<b>Create Date</b>	December 07, 2016
<b>Recall Status<sup>1</sup></b>	Open <sup>3</sup> , Classified
<b>Recall Number</b>	Z-0717-2017
<b>Recall Event ID</b>	<u>75620</u> <sup>23</sup>
<b>510(K)Number</b>	<u>K083739</u> <sup>24</sup>
<b>Product Classification</b>	<u>Material, impression</u> <sup>25</sup> - <u>Product Code ELW</u> <sup>26</sup>
<b>Product</b>	Virtual XD Refill Light Body Fast Set Wash Material, 2X50 ml, REF #/Product Code 646461, Rx ONLY -- product Usage: Dental impression material
<b>Code Information</b>	Lot No./Expiration Date: UL2395/June 28, 2018; UL2293/Dec 31, 2017; UL2222/Aug 28, 2017; UL2220/July 28, 2017; TL4121/ Mar 28, 2017.
<b>Recalling Firm/Manufacturer</b>	Ivoclar Vivadent, Inc. 175 Pineview Dr Amherst NY 14228-2231
<b>For Additional Information Contact</b>	Ivoclar Vivadent Customer Service 800-533-6825
<b>Manufacturer Reason for Recall</b>	The firm received complaints claiming the dental material failed to set up. As the dental material ages, the set time may increase.
<b>FDA Determined Cause<sup>2</sup></b>	Under Investigation by firm
<b>Action</b>	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.
<b>Quantity in Commerce</b>	US: 4659 units, Canada: 729 units
<b>Distribution</b>	Worldwide Distribution - US Nationwide and the countries of Canada and Australia
<b>Total Product Life Cycle</b>	TPLC Device Report <sup>27</sup>

<sup>1</sup> 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](#)<sup>28</sup>.

<sup>2</sup> Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

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



[FDA Home](#)<sup>3</sup> [Medical Devices](#)<sup>4</sup> [Databases](#)<sup>5</sup>

**Class 2 Device Recall Virtual XD**

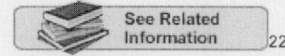


[510\(k\)](#)<sup>6</sup> | [DeNovo](#)<sup>8</sup> | [Registration & Listing](#)<sup>9</sup> | [Adverse Events](#)<sup>10</sup> | [Recalls](#)<sup>11</sup> | [PMA](#)<sup>12</sup> | [HDE](#)<sup>13</sup> | [Classification](#)<sup>14</sup> | [Standards](#)<sup>15</sup> | [CFR Title](#)<sup>21</sup> | [Radiation-Emitting Products](#)<sup>17</sup> | [X-Ray Assembler](#)<sup>18</sup> | [Medsun Reports](#)<sup>19</sup> | [CLIA](#)<sup>20</sup> | [TPLC](#)<sup>21</sup>

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[Back to Search Results](#)

**Class 2 Device Recall Virtual XD**



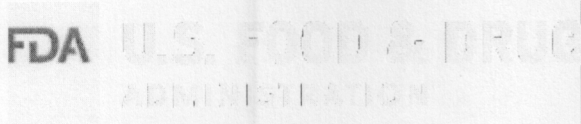
<b>Date Initiated by Firm</b>	November 09, 2016
<b>Create Date</b>	December 07, 2016
<b>Recall Status</b> <sup>1</sup>	Open <sup>3</sup> , Classified
<b>Recall Number</b>	Z-0718-2017
<b>Recall Event ID</b>	<a href="#">75620</a> <sup>23</sup>
<b>510(K)Number</b>	<a href="#">K083739</a> <sup>24</sup>
<b>Product Classification</b>	<a href="#">Material, impression</a> <sup>25</sup> - <b>Product Code</b> <a href="#">ELW</a> <sup>26</sup>
<b>Product</b>	Virtual XD Refill Light Body Regular Set Wash Material, 2X50 ml, REF #/Product Code 646462, Rx ONLY --  Product Usage: Dental impression material
<b>Code Information</b>	Lot No./Expiration Date: UL2221/July 28, 2017; TL4056/Nov 28, 2016
<b>Recalling Firm/Manufacturer</b>	Ivoclar Vivadent, Inc. 175 Pineview Dr Amherst NY 14228-2231
<b>For Additional Information Contact</b>	Ivoclar Vivadent Customer Service 800-533-6825
<b>Manufacturer Reason for Recall</b>	The firm received complaints claiming the dental material failed to set up. As the dental material ages, the set time may increase.
<b>FDA Determined Cause</b> <sup>2</sup>	Under Investigation by firm
<b>Action</b>	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.
<b>Quantity in Commerce</b>	US: 1867 units, Canada: 465 units
<b>Distribution</b>	Worldwide Distribution - US Nationwide and the countries of Canada and Australia
<b>Total Product Life Cycle</b>	<a href="#">TPLC Device Report</a> <sup>27</sup>

<sup>1</sup> 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](#)<sup>28</sup>.

<sup>2</sup> Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

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





[FDA Home](#)<sup>3</sup> [Medical Devices](#)<sup>4</sup> [Databases](#)<sup>5</sup>

**Class 2 Device Recall Virtual XD**

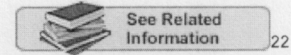


[510\(k\)](#)<sup>6</sup> | [DeNovo](#)<sup>8</sup> | [Registration & Listing](#)<sup>9</sup> | [Adverse Events](#)<sup>10</sup> | [Recalls](#)<sup>11</sup> | [PMA](#)<sup>12</sup> | [HDE](#)<sup>13</sup> | [Classification](#)<sup>14</sup> | [Standards](#)<sup>15</sup> | [CFR Title 21](#)<sup>16</sup> | [Radiation-Emitting Products](#)<sup>17</sup> | [X-Ray Assembler](#)<sup>18</sup> | [Medsun Reports](#)<sup>19</sup> | [CLIA](#)<sup>20</sup> | [TPLC](#)<sup>21</sup>

[New Search](#)

[Back to Search Results](#)

**Class 2 Device Recall Virtual XD**



<b>Date Initiated by Firm</b>	November 09, 2016
<b>Create Date</b>	December 07, 2016
<b>Recall Status</b> <sup>1</sup>	Open <sup>3</sup> , Classified
<b>Recall Number</b>	Z-0719-2017
<b>Recall Event ID</b>	<u>75620</u> <sup>23</sup>
<b>510(K)Number</b>	<u>K083739</u> <sup>24</sup>
<b>Product Classification</b>	<u>Material, impression</u> <sup>25</sup> - <b>Product Code</b> <u>ELW</u> <sup>26</sup>
<b>Product</b>	Virtual XD Test Pack Heavy/Light Fast Set, 2 x 50 ml, REF #/Product Code 646469, Rx ONLY --  Product Usage: Dental impression material
<b>Code Information</b>	Lot No./Expiration Date: TL4095/Jan 15, 2017; TL4094/Jan 15, 2017
<b>Recalling Firm/Manufacturer</b>	Ivoclar Vivadent, Inc. 175 Pineview Dr Amherst NY 14228-2231
<b>For Additional Information Contact</b>	Ivoclar Vivadent Customer Service 800-533-6825
<b>Manufacturer Reason for Recall</b>	The firm received complaints claiming the dental material failed to set up. As the dental material ages, the set time may increase.
<b>FDA Determined Cause</b> <sup>2</sup>	Under Investigation by firm
<b>Action</b>	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.
<b>Quantity in Commerce</b>	US: 2090 units, Canada: 331 units, Australia: 465 units
<b>Distribution</b>	Worldwide Distribution - US Nationwide and the countries of Canada and Australia
<b>Total Product Life Cycle</b>	TPLC Device Report <sup>27</sup>

<sup>1</sup> 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](#)<sup>28</sup>.

<sup>2</sup> Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

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