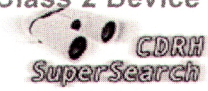




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**Class 2 Device Recall Legacy Full Contour Laboratory Abutment: 3.5mmD Platform/5.5mmD**

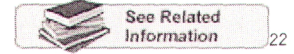


[510\(k\)](#)<sup>6</sup> | [DeNovo](#)<sup>8</sup> | [Registration & Listing](#)<sup>7</sup> | [Adverse Events](#)<sup>10</sup> | [Recalls](#)<sup>11</sup> | [PMA](#)<sup>12</sup> | [HDE](#)<sup>13</sup> | [Classification](#)<sup>14</sup> | [Standards](#)<sup>15</sup> | [CFR Title 21](#)<sup>16</sup> | [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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**Class 2 Device Recall Legacy Full Contour Laboratory Abutment: 3.5mmD Platform/5.5mmD**



<b>Date Initiated by Firm</b>	May 02, 2017
<b>Create Date</b>	May 22, 2017
<b>Recall Status<sup>1</sup></b>	Open <sup>3</sup> , Classified
<b>Recall Number</b>	Z-2125-2017
<b>Recall Event ID</b>	<u>77171</u> <sup>23</sup>
<b>510(K)Number</b>	<u>K061319</u> <sup>24</sup>
<b>Product Classification</b>	Implant, endosseous, root-form <sup>25</sup> - <b>Product Code DZE</b> <sup>26</sup>
<b>Product</b>	Legacy Full Contour Laboratory Abutment: 3.5mmD Platform/5.5mmD
<b>Code Information</b>	89103, 83493, 78986
<b>Recalling Firm/Manufacturer</b>	Implant Direct Sybron Manufacturing, LLC 3050 E Hillcrest Dr Westlake Village CA 91362-3171
<b>For Additional Information Contact</b>	818-444-3300 Ext. 3323
<b>Manufacturer Reason for Recall</b>	Implant Direct Sybron Manufacturing is recalling the Legacy Full-Contour Abutment 3.5mmD Assembly because it may be out of Implant Direct specification.
<b>FDA Determined Cause<sup>2</sup></b>	Nonconforming Material/Component
<b>Action</b>	Implant Direct sent an Urgent Medical Device Field Corrective recall letter dated April 2017 to all affected customers. The letter identified the product the problem and the action needed to be taken by the customer. Customers are informed that the product may be out of Implant Direct specification. The abutment should have a full hex configuration from end of part to shoulder (1.6mm). When the part is in-correct there will be a noticeable diameter ring just above shoulder and a hex flat face that appears short (@ 1.1mm) not allowing full engagement to implant analog. This discrepancy may lead to the possibility of the abutment not seating properly on the implant, and if undetected may lead to micro-leakage and a possible infection to the patient. Customers are instructed to complete and return the Acknowledgement and Recall Return form within 48 hrs. Customers with any questions are instructed to contact Implant Direct Sybron Manufacturing LLC Customer Care at 1-888-649-6425.
<b>Quantity in Commerce</b>	151 units
<b>Distribution</b>	Worldwide Distribution - Nationwide Distribution and to the countries of : European Union (HU, GB, DE, DK, IT, HR, FR), and Japan
<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