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

See Related Information 22

Date Initiated by Firm	May 02, 2017
Create Date	May 22, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-2125-2017
Recall Event ID	77171[23]
510(K)Number	K061319[24]
Product Classification	Implant, endosseous, root-form[25] - **Product Code** DZE[26]
Product	Legacy Full Contour Laboratory Abutment: 3.5mmD Platform/5.5mmD
Code Information	89103, 83493, 78986
Recalling Firm/ Manufacturer	Implant Direct Sybron Manufacturing, LLC 3050 E Hillcrest Dr Westlake Village CA 91362-3171
For Additional Information Contact	818-444-3300 Ext. 3323
Manufacturer Reason for Recall	Implant Direct Sybron Manufacturing is recalling the Legacy Full-Contour Abutment 3.5mmD Assembly because it may be out of Implant Direct specification.
FDA Determined Cause [2]	Nonconforming Material/Component
Action	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.
Quantity in Commerce	151 units
Distribution	Worldwide Distribution - Nationwide Distribution and to the countries of : European Union (HU, GB, DE, DK, IT, HR, FR), and Japan
Total Product Life Cycle	TPLC Device Report[27]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA