



Food and Drug Branch – Device Recalls

**CALIFORNIA DEVICE RECALL INFORMATION SHEET**

**Nobel Biocare recalls NobelReplace Endosseus Root-Form Implant**

Recall Date	Product Description	Recalling Firm	Recall Reason
12/17/2021	<b>NobelReplace Conical Connection</b> RP 4.3x11.5 mm REF 36707 STERILE R	<b>Nobel Biocare Usa llc</b> Yorba Linda, California	Due to 16 complaints related to drivers not engaging in implants. According to the firm's investigations, the incorrect offset gauge was potentially used during production of the implants. As a result, this could potentially lead to aborted or a delay in surgical procedure.

Recall Class	Product Identification	Distribution	Affected Dates
II	All Serial Numbers	88 Units for 25 Customers in California	July 2020 - August 2020

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