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510(k) SUMMARY

DENTSPLY

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TRADE NAME: DENTSPLY® PRECISION TORQUE SYSTEM

CLASSIFICATION NAME: Accessory to Endosseous Implants 21 CFR, 872.3640

PREDICATE DEVICE: Calcitek Torque Wrench System K931440

DEVICE DESCRIPTION: The DENTSPLY® PRECISION TORQUE SYSTEM utilizes a ratchet mechanism and a pre-calibrated disposable insert. Each time the wrench is used, a new breakaway insert provides for a 100% of re-calibration. Two different insert sizes are provided.

INTENDED USE: The DENTSPLY® PRECISION TORQUE SYSTEM is used for tightening of prosthetic implant components to their recommended torque levels to deliver an accurate torque application. The SYSTEM can also be used to unthread prosthetic screws.

TECHNOLOGICAL CHARACTERISTICS: The DENTSPLY® PRECISION TORQUE SYSTEM was evaluated for accuracy and reliability by examining the Torque Application and the Torque Calibration. The mean amount of torque that the new DENTSPLY® PRECISION TORQUE SYSTEM delivered for thirty samples (5 inserts) was 99.8% of the claimed 30 Ncm value, and well within the functional acceptance level that allowed for a maximum variance of $\pm 15\%$. For the competitors' products evaluated, the mean variance for the claimed application value ranged from 14.9% up to 31.4% when the tool was repeatedly used. Unique to the new DENTSPLY design, the DENTSPLY® PRECISION TORQUE SYSTEM maintained its precision calibration over time.

We believe that the performance data and the conceptual similarities to legally marketed competitive products demonstrate the safety and effectiveness of the DENTSPLY® PRECISION TORQUE SYSTEM for its intended uses.

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