December 19, 2024

Quickdent Devices Private Ltd.
℅ Angela Blackwell
Senior Consultant
Blackwell Device Consulting
P.O. Box 718
Gresham, Oregon 97030-0172

Re: K243094
Trade/Device Name: Quickdent Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: September 27, 2024
Received: September 30, 2024

Dear Angela Blackwell:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243094

Device Name
Quickdent Dental Implant System

Indications for Use *(Describe)*
The Quickdent Dental Implant System are endosseous implants intended to be surgically placed in the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient's esthetics and chewing function. Implants are intended for single or multiple unit restorations on splinted or non-splinted applications. Korticale TPR IH, Ossi Classic IH, Trabecos IH, Acti Fix CC and Kortifix Pro CC are intended for immediate loading when good primary stability is achieved, and with appropriate occlusive loading. These implants can also be used for loading after a conventional healing period. Trabecos 3.3 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible. Mandibular central and lateral incisors must be splinted if using two or more 3.3 implants adjacent to one another.

Korticale SP one piece implant is indicated for support and retention of fixed single tooth and fixed partial denture restorations in premolar, cuspid and incisor regions of partially edentulous jaws. Korticale SP one piece implants may be loaded immediately in the anterior mandibular arch if four implants are splinted together with a bar. Korticale SP one piece implants may be immediately restored with a temporary prosthesis that is not in functional occlusion.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510k Summary K243094
December 13, 2024
Quickdent Dental Implant System

Name and address: Quickdent Devices Private Ltd.
Unit No. 128, Kuber Complex
New Link Road S N of Village
Oshiwar Link Road, Andheri
West, Mumbai, Mumbai Suburban.
Maharashtra 400053 India
Contact Person: Dr. Mayur Khairnar
Email: quickdentindia@gmail.com
Name of device: Quickdent Dental Implant System
Classification Name: Endosseous dental implants
CFR: 21 CFR 872.3640
Primary Product Code: DZE
Secondary Product Code: NHA

Submission Contact:

Angela Blackwell
Blackwell Device Consulting
P.O. Box 718
Gresham, OR 97030-0172
(704)450-9934
angela@blackwelldevice.com

Device Description: The Quickdent Dental Implant System contains 3 designs of internal hex implants and various types of abutments as described below as well as 2 designs of conical implant with NP and RP platforms and abutments corresponding to both platforms. Additionally, a one piece implant is available. All devices are made from Ti-6AL-4V ELI unless otherwise noted. The implants have a grit blasted and acid etched surface. Conical abutments need to match the implant platform of narrow or regular. No abutments other than UCLA abutments are intended to be modified by the user.

Ossi Classic IH implants are tapered internal hex implants with more tightly spaced flat edge threads at the top and wider spaced flat edge threads in the lower tapered section. Ossi Classic IH comes in 3.5, 3.75, 4.2, 5.0 and 6.0 mm diameter with lengths of 8, 10, 11.5, 13, and 16mm (no 16mm in 6.0mm diameter).

Trabecos IH implants are cylindrical internal hex implants with evenly spaced threads which are flat edged at the top and sharp edged in the lower section. Trabecos comes in 3.3, 3.75, 4.2, 5.0, and 6.0 mm diameter with lengths of 8, 10, 11.5, 13, and 16mm (no 16mm in 5.0 or 6.0mm diameter). 3.3mm diameter implants are not for use with angled abutments in the posterior region of the mouth.

Korticale TPR IH are spiral internal hex implants with widely spaced threads. Korticale TPR IH comes in 3.5 and 4.2 mm diameter with lengths of 10, 12, 14 and 16mm.

Internal Hex Healing Abutments come in 4.5mm diameter with cuff heights of 2, 3, 4, 5, 6,7 mm. They come in narrow with a diameter 3.8mm with cuff heights of 3, 4, 5,6, 7 mm and wide with a diameter 5.5mm with cuff heights of 2,3,4,5,6,7 mm. Extra wide healing caps are 6.3mm diameter and come in cuff heights of 2,3,4,5 mm. An internal hex cover screw is also available. A healing cap for multi-units is available.

Internal Hex Straight Abutments have a 3.75mm interface diameter and come in 4.5mm diameter with total heights above the platform of 5,7,9,11,13,15 mm, and in 5.5mm diameter with heights above the platform of 9, 11, and 13 mm.
Internal Hex Straight Narrow Abutments have a 3.75mm interface area and come 3.75mm diameter with heights above the platform of 5,7,9, 11 mm.

Internal Hex Straight Shouldered Abutments come in 3.75mm interface diameter in 4.5 and 5.4 mm diameter with gingival heights of 1,2,3,4 mm.

Internal Hex Angled Abutments come in 15° 3.75mm diameter with height above platform of 9, and 11.4mm, and 25° 3.75mm diameter with height above platform of 8.5 mm.

Internal Hex Angled Anatomic Abutments come in 15° 3.75mm diameter with cuff heights of 1,2,3,4 mm and height above low side of shoulder of 8,9,10,11 mm and 25° 3.75mm diameter with cuff heights of 1,2,3,4 mm and height above platform of 8.3, 9.2, 10.3, 10.3 mm.

Internal Hex UCLA abutment bases come in 3.75mm diameter and use a Delrin plastic sleeve. The UCLA are for making straight restorations which are 4mm above the gingival collar and have a post height of no more than 12mm. The minimum wall thickness of the cast abutments is 0.3mm. The angulation, wall thickness and diameter of the UCLA base component are not intended to be modified.

Internal Hex Ball attachments come in 4.0mm diameter with cuff heights of 2, 3, 4, 5, 6, or 7mm.The ball attachments snap into a stainless steel housing which has a polyamide or polyether retention cap. The Retention Caps come in the colors yellow, pink and clear which represent 0.5, 0.9, and 1.3 kg retention levels. The retention caps allow implants to be within 14° of vertical and still snap into place.

Quickloc IH attachments come in 3.85mm diameter with cuff heights 1,2,3,4,5,6 mm. The Quickloc IH attachments snap into a Ti6AL4V ELI housing which has a polyamide, polyether or polyoxymethylene retention cap. The Retention Caps come in the colors yellow, pink, clear, purple which represent 0.6, 0.8, 1.0, 1.5 kg retention levels. The retention caps allow implants to be within 20° of vertical and still snap into place.

Internal Hex Straight Multi-Unit come in 4.8mm diameter with cuff heights of 1, 2, 3, 4, 5 mm.

Internal Hex Angled Multi-Units come in 17° and 30° with cuff heights of 1, or 2 mm.

Acti Fix CC implants are very slightly tapered conical implants with more tightly spaced flat edge threads at the top and wider spaced sharp edge threads in the lower tapered section. Acti Fix CC comes in 3.5 (NP), 4.3 (RP) and, 5.0 (RP) mm diameter with lengths of 8, 10, 11.5, 13, and 16mm.

Kortifix Pro CC are spiral conical implants with widely space threads. Kortifix Pro CC comes in 3.5 (NP) and 4.2 (RP) diameters in lengths of 10, 12, 14, and 16mm.

Conical healing caps come in NP and RP with cuff heights of 2,3,4,5 mm. NP and RP conical cover screws are also available. A healing cap for multi-units is available.

Conical straight abutments come in NP and RP with heights above platform of 9 or 13 mm.

Conical shoulder abutments come in NP and RP with gingival heights of 1,2,3 mm.

Conical angled shoulder abutments 15° come in NP and RP with cuff heights of 1,2,3 mm and total heights of 10.7, 12.2, 13.7 mm for NP and 11, 12, 13 mm for RP.

Conical angled shoulder abutments 25° come in NP and RP with cuff heights of 1,2,3 mm and total heights of 10.7, 12.2, 13.7 mm for NP and 11, 12, 13 mm for RP.

Conical ball attachments come in 3.5mm diameter for NP and 5.0mm diameter for RP with cuff heights of 1,2,3,4,5,6 mm. The ball attachments snap into a stainless steel housing which has a polyamide or polyether retention cap. The Retention Caps come in the colors yellow, pink and clear which represent 0.5, 0.9, and 1.3 kg retention levels. The retention caps allow implants to be within 14° of vertical and still snap into place.

Quicksnap CC attachments in 3.5mm diameter for NP and 5.0mm diameter for RP with cuff heights of 1,2,3,4 mm. The Quicksnap CC attachments snap into a Ti6AL4V ELI housing which has a polyamide, polyether or polyoxymethylene retention cap. The Retention Caps come in the colors yellow, pink, clear, purple which represent 0.6, 0.8, 1.0, 1.5 kg retention levels. The retention caps allow implants to be within 20° of vertical and still snap into place.

Conical straight multi-units in NP and RP are 4.8mm in diameter with cuff heights of 1,2,3,4,5 mm.

Conical NP and RP Angled Multi-Units come in 17° and 30° with cuff heights of 1, or 2 mm.

Korticale SP one piece implant comes in diameters of 3.5 and 4.2mm with lengths of 8, 10, 12, 14, and 16mm. The abutment portion has a 2mm gingival collar and a 7mm abutment post height above the gingival collar. Only straight models of Korticale SP are available with no available angular correction.

Indications for Use:
The Quickdent Dental Implant System are endosseous implants intended to be surgically placed in the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient's esthetics and chewing function. Implants are intended for single or multiple unit restorations on splinted or non-splinted applications. Korticale TPR IH, Ossi Classic IH, Trabecos IH, Acti Fix CC and Kortifix Pro CC are intended for immediate loading when good primary stability is achieved, and with appropriate occlusive loading. These implants can also be used for loading after a conventional healing period. Trabecos 3.3 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible. Mandibular central and lateral incisors must be splinted if using two or more 3.3 implants adjacent to one another.

Korticale SP one piece implant is indicated for support and retention of fixed single tooth and fixed partial denture restorations in premolar, cuspid and incisor regions of partially edentulous jaws. Korticale SP one piece implants may be loaded immediately in the anterior mandibular arch if four implants are splinted together with a bar. Korticale SP one piece implants may be immediately restored with a temporary prosthesis that is not in functional occlusion.

Testing Summary: Dynamic fatigue testing according to ISO 14801 was conducted to determine the abutments and implants are strong enough for their intended use. Cytotoxicity testing according to ISO 10993 was done on both implants and abutments. Skin sensitization testing according to ISO 10993-10:2021 was conducted on implants. Irritation testing according to ISO 10993-23:2021 was conducted on implants. Steam sterilization validation was conducted according to ISO 17665-1. Bacterial endotoxin testing was conducted according to ANSI/AAMI ST72:2019 and USP <161>. Gamma irradiation validation was conducted according to ISO 11137-2. Package testing was conducted according to ASTM D999-08, ASTM F3039-13, and ASTM D5276-98(2009) and then shelf life testing was conducted according to ASTM F1929-12, and ASTM F1980-07. Testing of the modified surface included testing for organic carbon, hydrocarbons, and SEM/EDX. All were within the limits based on relevant standards set in the cleaning validation protocol.

MR Environment Condition

Non-clinical worst-case MRI review was performed to evaluate the metallic QUickdent Dental Implant System devices in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795), based on the entire system including all variations (all compatible implant bodies, dental abutments, and fixation screws) and material composition. Rationale addressed parameters per the FDA guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment," including magnetically induced displacement force and torque.

Primary Predicate Device: TOV Dental Implant System K240837
Reference Predicates: Zimmer One Piece Implant K052997

Substantial Equivalence:

The Quickdent Dental Implant System is substantially equivalent to TOV Dental Implants in indications for use, materials, design, and fatigue performance. Slight differences in implant design between the subject devices and the predicate devices were addressed by the reference devices.

Company & Device Name	Quickdent Dental Implant System	TOV Dental Implant System K240837 Predicate device	Zimmer One Piece Implant K052997 Predicate for Korticale SP
Indications for Use	The Quickdent Dental Implant System are endosseous implants intended to be surgically placed in the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient's esthetics and chewing function. Implants are intended for single or multiple unit restorations on splinted or non-splinted applications. Korticale TPR IH, Ossi Classic IH, Trabecos IH, Acti Fix CC and Kortifix Pro CC are intended for immediate loading when good primary stability is achieved, and with appropriate occlusive loading.	The TOV Dental Implant System are endosseous implants intended to be surgically placed in the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient's esthetics and chewing function. Implanet implants are intended for single or multiple unit restorations on splinted or non-splinted applications. Maer, Ragil and TCX are intended for immediate loading when good primary stability is achieved, and with appropriate occlusive loading. These implants can also be used for loading after a conventional healing period.	Zimmer® One-Piece implants are indicated for the support and retention of fixed single tooth and fixed partial denture restorations in the premolar, cuspid, and incisor regions of partially edentulous jaws. Zimmer® One-Piece implants may be loaded immediately in the anterior mandibular arch if four are splinted together with a bar. The Zimmer® One-Piece implant may be immediately restored with a temporary prosthesis that is not in functional occlusion.

	These implants can also be used for loading after a conventional healing period. Trabecos 3.3 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible. Mandibular central and lateral incisors must be splinted if using two or more 3.3 implants adjacent to one another. Korticale SP one piece implant is indicated for support and retention of fixed single tooth and fixed partial denture restorations in premolar, cuspid and incisor regions of partially edentulous jaws. Korticale SP one piece implants may be loaded immediately in the anterior mandibular arch if four implants are splinted together with a bar. Korticale SP one piece implants may be	Ragil 3.3 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible. Mandibular central and lateral incisors must be splinted if using two or more 3.3 implants adjacent to one another.	

	immediately restored with a temporary prosthesis that is not in functional occlusion.		
Implant Diameters	Ossi Classic IH 3.5, 3.75, 4.2, 5.0, 6.0 mm Trabecos IH 3.3, 3.75, 4.2, 5.0, 6.0 mm Korticale TPR IH 3.5, 4.2 Acti Fix CC 3.5, 4.3, 5.0 mm NP = 3.5 RP = 4.3, 5.0 Kortifix Pro CC 3.5 (NP), 4.2 (RP) Korticale SP 3.5, 4.2mm	Maer 3.5, 3.75, 4.2, 5.0, 6.0 mm Ragil 3.3, 3.75, 4.2, 5.0, 6.0 mm TCX 3.5, 4.3, 5.0 mm NP = 3.5 RP = 4.3, 5.0	One Piece 3.7, 4.7 mm
Implant Lengths	Ossi Classic IH 8, 10, 11.5, 13,16mm (no 16mm in 6.0mm diameter) Trabecos IH 8, 10, 11.5, 13, and 16mm (no 16mm in 5.0 or 6.0mm diameter) Korticale TPR IH 10, 12, 14, 16mm Acti Fix CC 8, 10, 11.5, 13,16mm	Maer 8, 10, 11.5, 13,16mm (no 16mm in 6.0mm diameter) Ragil 8, 10, 11.5, 13, and 16mm (no 16mm in 5.0 or 6.0mm diameter) TCX 8, 10, 11.5, 13,16mm	One Piece 10, 11.5, 13, 16mm

	Kortifix Pro CC 10, 12, 14, 16mm Korticale SP 8, 10, 12, 14, 16mm		
Material of devices included in the submission	Ti-6AL-4V ELI	Ti-6AL-4V ELI	Ti-6AL-4V ELI
Type of abutment and maximum angulation	Pre-manufactured of no more than 30°	Pre-manufactured of no more than 30°	
Interface type/shape	Internal hex, conical	Internal hex, conical	N/A
ISO 14801 Fatigue Testing	Sufficient run out load for their intended use	Sufficient run out load for their intended use	
Surface Treatment	SLA	SLA	RBM and acid wash
Post Surface Treatment Cleanliness Demonstrated	Yes	Yes	Yes

Cover screw	Cover screw for IH NP and RP	Cover screw for IH NP and RP
Multi-Unit Abutments in IH, NP and RP	4.8 mm diameter multi-units in IH, NP and RP with cuff heights of 1,2,3,4,5mm	4.8 mm diameter multi-units in IH, NP and RP with cuff heights of 1,2,3,4,5mm
17° and 30° Angled Multi-Unit Abutments IH, NP and RP	17° and 30° Angled Multi-Unit Abutments IH, NP and RP with platform heights of 1,2 mm	17° and 30° Angled Multi-Unit Abutments IH, NP and RP with platform heights of 1,2 mm
Locator Abutments with metal housing and retention cap allowing 20° divergence of the implants	Quickloc IH/Quicksnap CC attachments IH (3.85mm), NP and RP (3.9mm) Cuff heights of 1, 2, 3, 4, 5, 6 mm (5 and 6 only in IH)	Double Loc / Conical Retentor attachments IH (3.85mm), NP and RP (3.9mm) Cuff heights of 1, 2, 3, 4, 5, 6 mm (5 and 6 only in IH)

	Ti6Al4V ELI housing Polyamide, polyether or polyoxymethylene retention cap with retention levels from 0.6to 1.5 kg	Ti6Al4V ELI housing Polyamide, polyether or polyoxymethylene retention cap with retention levels from 0.6to 1.5 kg
Ball attachments with metal housing and retention cap allowing 14° divergence of the implants	ball attachments IH (4.00mm diameter), NP (3.5mm diameter) and RP (5.0mm diameter) Cuff heights of 2, 3, 4, 5, 6, 7 mm for IH and 1.2.3.4.5.6 mm for NP and RP Stainless steel 316 housing Polyamide or polyether retention cap with retention levels from 0.5 to 1.3 kg	ball attachments IH (4.00mm diameter), NP (3.5mm diameter) and RP (5.0mm diameter) Cuff heights of 2, 3, 4, 5, 6, 7 mm for IH and 1.2.3.4.5.6 mm for NP and RP Stainless steel 316 housing Polyamide or polyether retention cap with retention levels from 0.5 to 1.3 kg
Healing Caps 3.8mm	IH 3.8mm diameter healing cap in 3,4,5,6,7 mm cuff height 3.75 diameter NP healing cap in 2,3,4,5 mm cuff heights	IH 3.8mm diameter healing cap in 3,4,5,6,7 mm cuff height 3.75 diameter NP healing cap in 2,3,4,5 mm cuff heights
Healing Caps 4.6 diameter standard	IH 4.5mm diameter healing cap in 2,3,4,5,6,7 mm cuff height 4.5 mm diameter RP healing cap with cuff heights 2,3,4,5 mm.	IH 4.5mm diameter healing cap in 2,3,4,5,6,7 mm cuff height 4.5 mm diameter RP healing cap with cuff heights 2,3,4,5 mm.

Healing Caps 5.5 diameter wide	IH 5.5mm diameter healing abutment in 2,3,4,5,6,7 mm cuff height	IH 5.5mm diameter healing abutment in 2,3,4,5,6,7 mm cuff height
Healing Cap 6.3mm diameter	IH 6.3mm diameter healing abutment in 2,3,4,5 mm cuff height	IH 6.3mm diameter healing abutment in 2,3,4,5 mm cuff height
Straight Abutment	IH 4.5mm diameter abutment with heights above platform of 5, 7,9,11,13,15 mm NP and RP 4.5mm diameter with heights above platform of 9 and 13 mm	IH 4.5mm diameter abutment with heights above platform of 5, 7,9,11,13,15 mm NP and RP 4.5mm diameter with heights above platform of 9 and 13 mm
Straight Narrow Abutment	IH 3.75mm diameter abutment with total heights of 5,7,9, 11 mm	IH 3.75mm diameter abutment with total heights of 5,7,9, 11 mm
Straight Wide Abutment	IH 5.5mm diameter abutment with total heights of 9,11 or 13 mm	IH 5.5mm diameter abutment with total heights of 9,11 or 13 mm
Shoulder Abutment	4.5 diameter IH, NP, RP shoulder abutment with shoulder heights of 1,2,3,4 mm (4 only in IH) IH total heights of 10.9, 11.9, 12.9, 13.9 mm NP and RP total heights of 11.8, 12.6, and 13.6mm	4.5 diameter IH, NP, RP shoulder abutment with shoulder heights of 1,2,3,4 mm (4 only in IH) IH total heights of 10.9, 11.9, 12.9, 13.9 mm NP and RP total heights of 11.8, 12.6, and 13.6mm

	5.4mm diameter IH shoulder abutment with shoulder heights of 1.2.3.4 mm and total heights of 10.7, 11.7, 12.17 and 13.7 mm	5.4mm diameter IH shoulder abutment with shoulder heights of 1.2.3.4 mm and total heights of 10.7, 11.7, 12.17 and 13.7 mm
15° Angled Abutment	3.75mm diameter IH 15° angled abutment with total heights of 9 or 11.4 mm	3.75mm diameter IH 15° angled abutment with total heights of 9 or 11.4 mm
25° Angled Abutment	3.75mm diameter IH 25° angled abutment with total height of 8.5 mm	3.75mm diameter IH 25° angled abutment with total height of 8.5 mm
Shouldered 15° Angled Abutment Hex, Conical NP, and RP	IH 3.75mm diameter 15° Angled Shoulder Abutment with cuff heights of 1,2,3,4 mm and height above low side of shoulder 8,9,10,11 mm NP and RP 15° Angled Shoulder Abutment with cuff heights of 1,2,3 mm and total heights of 10.7, 12.2 and 13.7 mm & 11, 12, 13 mm	IH 3.75mm diameter 15° Angled Shoulder Abutment with cuff heights of 1,2,3,4 mm and height above low side of shoulder 8,9,10,11 mm NP and RP 15° Angled Shoulder Abutment with cuff heights of 1,2,3 mm and total heights of 10.7, 12.2 and 13.7 mm & 11, 12, 13 mm
Shouldered 25° Angled Abutment Hex, Conical NP and RP	IH 3.75mm diameter 25° Angled Shoulder Abutment with cuff heights of 1,2,3,4 mm with heights above platform of 8.3,9.2,10.3,10.3 mm	IH 3.75mm diameter 25° Angled Shoulder Abutment with cuff heights of 1,2,3,4 mm with heights above platform of 8.3,9.2,10.3,10.3 mm

	NP and RP 25° Angled Shoulder Abutment with cuff heights of 1,2,3 mm with total heights of 10.7, 12.2, and 13.7 mm & 11, 12, 13mm	NP and RP 25° Angled Shoulder Abutment with cuff heights of 1,2,3 mm with total heights of 10.7, 12.2, and 13.7 mm & 11, 12, 13mm
UCLA Base Ti	4.5mm diameter UCLA base in hexed	4.5mm diameter UCLA base in hexed

Conclusion:

Quickdent Dental Implant System is substantially equivalent to TOV Dental Implant System. They both have the same indications for use, are of the same material, and have internal hex and conical connections. The abutments, healing caps, and angled abutments are offered in similar designs and heights. Quickdent and TOV have the same types of performance testing with similar results. Performance testing demonstrates substantial equivalence to the identified predicate devices.