J & P Dental Technologies
c/o Angela Blackwell
Senior Consultant
Blackwell Device Consulting
P.O. Box 718
Gresham, Oregon 97030-0172

March 26, 2024

Re: K231132
Trade/Device Name: J & P Click Attachments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: February 27, 2024
Received: February 28, 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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231132

Device Name
J & P Click Attachments

Indications for Use *(Describe)*
J & P Click Attachments are designed to support fixed, partial or full arch restorations on endosseous dental implants in the mandible or maxilla for the purpose of restoring masticatory function. They are used in fixed hybrid restorations that can be attached with a click in system. Click attachments are indicated for use with vertical implant placements.
They are indicated for the following implant systems:
Biohorizons Tapered Tissue Level implants in diameters 3.8, 4.2, 4.6, 5.2 mm
Nobel Biocare NobelActive including 3.5, 4.3, 5.0 mm diameter NobelActive, 3.75, 4.3, 5.0mm diameter NobelParallel and 3.5, 4.3, 5.0mm diameter NobelReplace Conical Connection Implants
Implant Direct Legacy 3 for 3.7, 4.2, 4.7, 5.2mm diameter implants
Surgikor Versatile for 3.5, 3.75, 4.2, 4.5, 5.0, 6.0mm diameter implants
Surgikor Fixation for 3.5, 3.9, 4.3, 5.0mm diameter implants
Surgikor Solution for 3.5, 4.0, 4.5, 5.0, 5.5, 6.0mm diameter implants
Neodent Grand Morse for 3.5, 3.75, 4.0, 4.3 and 5.0 mm diameter implants
MIS Seven for implant diameters 3.75, 4.2, 5, and 6mm
Zimmer for Tapered Screw-Vent in 3.7, 4.1 and 4.7mm implant diameter
Hiossen ETIII for 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, and 7.0mm implant diameters

SIN Cone Morse 11.5° and 16° implant lines
11.5° Strong SW/SW Plus implant diameters 3.5, 3.8, 4.5, 5.0mm Unitite implant diameters 3.5, 4.0,4.3, 5.0, 6.0 Tryon CM Conical implant diameters 3.5, 4.5, 5.0 Tryon CM Cylindrical implant diameters 3.5, 3.75, 4.0, 5.0 Epikut CM/CM Plus implant diameters 3.5, 3.8, 4.0, 4.5, 5.0
16 ° Strong SW CM/CM Plus implant diameters 3.5, 3.8, 4.5 and 5.0mm Epikut S/S Plus implant diameters 3.5, 3.8, 4.0, 4.5, 5.0mm

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 K231132
March 25, 2024
J & P Click Attachments

Name and address: J & P Dental Technologies
1527 W State Hwy 114 Ste 500-280
Grapevine, TX 76051
Contact Person: Dr. Aaron Paz
Phone Number: (310) 877-9858
Name of device: J & P Click Attachments
Classification Name: Endosseous dental implant abutments
CFR: 21 CFR 872.3630
Primary Product Code: NHA
Primary Predicate Device: Zest Anchors K220252 High Retention Attachment System
Reference Predicates: Nobel Biocare Nobel Active K142260 Allied Dental Solutions K152845
Implant Direct K192221 Legacy 3 and Interactive
SIN K221453 Epikut CM and K222231 Epikut S
MIS K040807 Seven
Biohorizons K071638 Tapered Tissue Level implant
Neodent K203382 Neodent GM Implants
Zimmer K160398 Tapered Screw Vent
Hiossen K140934 ET III
Surgikor K182615 Surgikor Dental Implant System

Submission Contact:

Angela Blackwell
Blackwell Device Consulting
P.O. Box 718
Gresham, OR 97030-0172
(704)450-9934
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Device Description: J & P Click Attachments provide a rigid connection of fixed, partial and full arch restorations (fixed/detachable hybrid dentures) to endosseous dental implants. They consist of abutments, attachment housings, and inserts. The abutments are provided in various OEM implant and abutment connections. The abutments are made from Ti-6AL-4V ELI which meets ASTM F136. All varieties of click attachments come in collar heights of 1, 2, 3, 4, 5 and 6mm. Abutment platform diameters include:

Biohorizons 3.5, and 4.5mm

Nobel Biocare Nobel Active 3.5 and 3.9mm (NobelParallel and NobelReplace Conical Connection are the same)
Implant Direct Legacy 3.5 and 4.5mm
Surgikor Versatile 3.5 and 4.5mm
Surgikor Fixation and Solution 3.5 and 3.9mm
Neodent Grand Morse 3.0mm
MIS Seven 3.5 and 4.5mm
Zimmer for Tapered ScrewVent 3.5 and 4.5mm
Hiossen ETIII 3.35mm
SIN 2.5mm for 11.5° cone morse and 2.72 mm for 16° cone morse

Indications for Use:
J & P Click Attachments are designed to support fixed, partial or full arch restorations on endosseous dental implants in the mandible or maxilla for the purpose of restoring masticatory function. They are used in fixed hybrid restorations that can be attached with a click in system. Click attachments are indicated for use with vertical implant placements.

They are indicated for the following implant systems:

Biohorizons Tapered Tissue Level implants in diameters 3.8, 4.2, 4.6, 5.2 mm

Nobel Biocare NobelActive including 3.5, 4.3, 5.0 mm diameter NobelActive,3.75, 4.3, 5.0mm diameter NobelParallel and 3.5, 4.3, 5.0mm diameter NobelReplace Conical Connection Implants

Implant Direct Legacy 3 for 3.7, 4.2, 4.7, 5.2mm diameter implants

Surgikor Versatile for 3.5, 3.75, 4.2, 4.5, 5.0, 6.0mm diameter implants

Surgikor Fixation for 3.5, 3.9, 4.3, 5.0mm diameter implants

Surgikor Solution for 3.5, 4.0, 4.5, 5.0, 5.5, 6.0mm diameter implants

Neodent Grand Morse for 3.5, 3.75, 4.0, 4.3 and 5.0 mm diameter implants

MIS Seven for implant diameters 3.75, 4.2, 5, and 6mm

Zimmer for Tapered Screw-Vent in 3.7, 4.1 and 4.7mm implant diameter

Hiossen ETIII for 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, and 7.0 mm implant diameters

SIN Cone Morse 11.5° and 16° implant lines
11.5° Strong SW/SW Plus implant diameters 3.5, 3.8, 4.5, 5.0mm Unitite implant diameters 3.5, 4.0,4.3, 5.0, 6.0 Tryon CM Conical implant diameters 3.5, 4.5, 5.0 Tryon CM Cylindrical implant diameters 3.5, 3.75, 4.0, 5.0 Epikut CM/CM Plus implant diameters 3.5, 3.8, 4.0, 4.5, 5.0

16 ° Strong SW CM/CM Plus implant diameters 3.5, 3.8, 4.5 and 5.0mm Epikut S/S Plus implant diameters 3.5, 3.8, 4.0, 4.5, 5.0mm

Testing Summary: Abutment steam sterilization validation was done according to ISO 17665-1. Cytotoxicity testing was conducted according to ISO 10993-5. Reverse engineering tolerance analyses were conducted for all OEM implant systems in the indications for use. These analyses covered the entire OEM implant system and included OEM implant body models, OEM abutment models and OEM abutment screw models.

MR Environment Condition

Non-clinical worst-case MRI review was performed to evaluate the metallic J & P Click Attachment 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.

Substantial Equivalence:

Click attachments are substantially equivalent to Zest High Retention Attachments abutments in indications for use, materials, design, and implant system compatibility.

Abutment Comparison Table	J & P Click Attachments	Zest High Retention Attachments K220252
Sterilization of abutments	Provided non-sterile with instructions for user to sterilize them	Provided non-sterile with instructions for user to sterilize them
Abutments available for these implant systems	Nobel Active implant diameters 3.5, 4.3, and 5.00mm NobelParallel implant diameters 3.75, 4.3, and 5.0mm NobelReplace implant diameters 3.5, 4.3 and 5.0mm Biohorizons Tapered Tissue Level implant diameters 3.8, 4.6mm Implant Direct Legacy 3 implant diameters 3.7, 4.2, 4.7, 5.2mm Surgikor Versatile for 3.5, 3.75, 4.2, 4.5, 5.0, 6.0mm diameter implants	Nobel Active implant diameters 3.5, 4.3, 5.5mm Biohorizons Tapered Tissue Level implant diameters 3.8, 4.6mm Implant Direct Legacy 3 implant diameters 3.7, 4.2, 4.7, 5.2, 5.7mm Neodent Grand Morse implant diameters 3.5, 3.75, 4.0, 4.3 and 5.0 mm MIS Seven implant diameters 3.75, 4.2, 5.0, 6.0mm

	Surgikor Fixation for 3.5, 3.9, 4.3, 5.0mm diameter implants Surgikor Solution for 3.5, 4.0, 4.5, 5.0, 5.5, 6.0mm diameter implants Neodent Grand Morse implant diameters 3.5, 3.75, 4.0, 4.3 and 5.0 mm MIS Seven implant diameters 3.75, 4.2, 5, and 6mm Zimmer Tapered Screw-Vent implant diameters 3.7, 4.1 and 4.7mm Hiossen ETIII 3.5, 4.0, 4.5, 5.0, and 5.5mm implant diameters SIN Cone Morse 11.5° and 16° implant lines 11.5° Strong SW/SW Plus implant diameters 3.5, 3.8, 4.5, 5.0mm Unitite implant diameters 3.5, 4.0,4.3, 5.0, 6.0 Tryon CM Conical implant diameters 3.5, 4.5, 5.0 Tryon CM Cylindrical implant diameters 3.5, 3.75, 4.0, 5.0 Epikut CM/CM Plus implant diameters 3.5, 3.8, 4.0, 4.5, 5.0 16 ° Strong SW CM/CM Plus implant diameters 3.5, 3.8, 4.5 and 5.0mm Epikut S/S Plus implant diameters 3.5, 3.8, 4.0, 4.5, 5.0mm	Zimmer Tapered Screw-vent implant diameters 3.7, 4.1, 4.7 and 6.00mm Hiossen ET III implant diameters 3.5, 4.0, 4.5, 5.0, 6.0, 7.0mm
Abutments are available in the following platform and gingival height descriptions	Neodent GM Interface with gingival heights of 1,2,3,4,5,6mm Hiosen ETIII Mini and Regular Interfaces with gingival heights of 1,2,3,4,5,6mm Biohorizons Tapered Pro 3.5 Interface/MIS Seven Standard Interface/Zimmer 3.5 Interface/Implant Direct Legacy 3.5	Neodent GM Interface with gingival heights of 1,2,3,4,5,6mm Hiosen ETIII Mini and Regular Interfaces with gingival heights of 1,2,3,4,5,6mm Biohorizons Tapered Pro 3.5 Interface/MIS Seven Standard Interface/Zimmer 3.5 Interface/Implant Direct Legacy 3.5

	Interface/Surgikor Hex Interface with gingival heights of 1,2,3,4,5,6mm Biohorizons Tapered Pro Wide interface/MIS Seven Wide Interface/Zimmer 4.5 interface/Implant Direct Legacy Wide Interface with gingival heights of 1,2,3,4,5,6mm Nobel Active NP Interface/Surgikor RC Interface with gingival heights of 1,2,3,4,5,6mm Nobel Active RP Interface/Surgikor WC Interface with gingival heights of 1,2,3,4,5,6mm SIN 11.5° Cone Morse and 16° Cone Morse with gingival heights of 1,2,3,4,5,6mm	Interface/Surgikor Hex Interface with gingival heights of 0, 1, 2.5, 3.5, 4.5, 5.5, 6.5mm Biohorizons Tapered Pro Wide interface/MIS Seven Wide Interface/Zimmer 4.5 interface/Implant Direct Legacy Wide Interface with gingival heights of 0,1,2,3,4,5,6mm Nobel Active NP Interface/Surgikor RC Interface with gingival heights of 1,2,3,4,5,6mm Nobel Active RP Interface/Surgikor WC Interface with gingival heights of 1,2,3,4,5,6mm
Indications for Use	J & P Click Attachments are designed to support fixed, partial or full arch restorations on endosseous dental implants in the mandible or maxilla for the purpose of restoring masticatory function. They are used in fixed hybrid restorations that can be attached with a click in system. Click attachments are indicated for use with vertical implant placements.	The High Retention Attachment System is designed to support fixed, partial or full arch restorations on endosseous dental implants in the mandible or maxilla for the purpose of restoring masticatory function. It is used in fixed hybrid restorations that can be attached with a snap-in system.
Material	Ti6Al4V	Ti6Al4V
Mechanism of action	Used with various dental implant systems to make fixed hybrid restorations.	Used with various dental implant systems to make fixed hybrid restorations.

Conclusion:

J & P Click Attachments are substantially equivalent to Zest High Retention Attachments. They both have the same indications for use (other than the vertical implant placement restriction), same mechanism of action, are of the same material, have the similar implant system compatibilities, and similar platform interfaces and gingival heights. Vertically placed implants are included in the indications for the predicate device so the indications for the subject device are a subset of those of the predicate. The

indications only being a subset of the predicate indications do not change the substantial equivalence because the restriction is there to make the devices safer and it does not change the other parts of the indications for use. Those interfaces not found in the predicate device are found in reference devices. The attachment designs are very similar between the predicate device and the current submission. Any differences in attachment design are slight differences in the dimensions which do not change the substantial equivalence of the two devices.