CMP Industries LLC
Devon Howe
President and CEO
413 N. Pearl St.
Albany, New York 12207

October 25, 2017

Re: K170423
Trade/Device Name: DentureID Microchip
Regulation Number: 21 CFR 880.6300
Regulation Name: Implantable Radiofrequency Transponder System For Patient Identification And Health Information
Regulatory Class: Class II
Product Code: PYQ, OUG
Dated: August 8, 2017
Received: August 10, 2017

Dear Devon Howe:

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mary S. Runner -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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510(k) Summary
for
DentureID Microchip
K170423/S001

1. Applicant

Submitter's Name: Devon Howe

Date Summary Prepared: Revised August 7, 2017

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2. Device Name

Proprietary Name: DentureID Microchip
Common Name: RFID Tag ISO 14443 micro-transponder embedded into medical grade epoxy
Classification Name: Implantable Radiofrequency Transponder System for Patient Identification and Health Information (21 CFR 880.6300)
Product Code: PYQ
Device Class: 2 (special controls)

3. Predicate Devices

Primary: VeriChip implantable radio frequency transponder system (DEN040007) by VeriChip Corporation (now called PositiveID) and purchased by Jamm Technologies

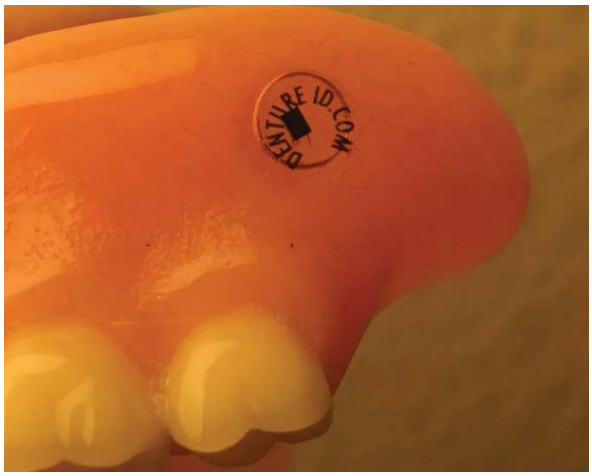
- **Common Name**: RFID Tag ISO 11784/85 micro-transponder
- **Classification Name**: Implantable Radiofrequency Transponder System for Patient Identification and Health Information (21 CFR 880.6300)
- **Product Code**: NRV
- **Device Class**: 2 (special controls)

Reference: SMARTSPONGE SYSTEM (K071355) by ClearCount Medical Solutions, Inc. now marketed by Medline Industries, Inc.

- **Common Name**: RFID Tag ISO 15693 micro-transponder embedded into medical grade epoxy and sewn into surgical sponge
- **Classification Name**: Surgical sponge scale (21 CFR 880.2740)
- **Product Code**: LWH

- **Device Class**: 1

4. Device Description



DentureID Microchip placed on the buccal flange of a denture

A. Overview: DentureID Microchip enables access to secure patent identification and device information when used with removable oral appliances. Denture identification is required by many US state governments because dentures are frequently lost. DentureID.com complies with these regulations by discreetly using a microchip instead of a visible patient name. The microchip is permanently embedded into a denture and is a digital link to owner contact information and information about the denture in the event that a repair or replacement is needed. All of the information is controlled on the secure DentureID.com website by the denture owner and dental professional. This information could be important to identify and contact the owner if a denture is found. Also, if a denture requires repair, this information will be extremely valuable to a dentist or denturist who must match the size and color of denture teeth, denture base or implant/attachment components. The DentureID Microchip can be read by any NFC compatible Android Smart Phone (after downloading the DentureID.com App from Google Play) and holding the phone against the microchip. The information on the DentureID.com website may be modified at any time by the patient or dental professional by entering a username and password. The information that is on the website will appear on the smart phone when reading the DentureID Microchip.
The DentureID Microchip is not a tracking system so it will not help in finding a lost denture. It is passive and does not emit any signal until powered by a compatible Smart Phone using NFC (near field communication).

B. Explanation of How the Device Functions: DentureID Microchips are classified as RFID ISO 14443 which use NFC (near-field-communication). DentureID Microchips are designed to be read by ISO 14443 NFC-compliant smart phones with DentureID App installed. A password is not required to read the microchip, however, intimate contact between the smart phone and the microchip is required. The NFC-compliant smart phone emits a low level of energy which “activates” the DentureID Microchip when placed within intimate contact. The DentureID Microchip responds to the SmartPhone with its serial number. The SmartPhone then requests the information associated with the microchip serial number stored on the DentureID website. The website returns the stored information and displays it on the SmartPhone. Because there is no significant patient risk if the App malfunctions, this App is not considered a “Mobile Medical App.”

DentureID Microchips are encased in a medical-grade epoxy resin. The size is 1.5mm X 6 mm in diameter. They are inserted into the buccal flange of a denture and completely covered with self-cure repair resin. The DentureID Microchip does not directly contact the patient. The process to insert the microchip into a denture is performed with lower labor cost as compared to conventional denture identification methods, and it satisfies denture identification regulations required in 27 US States and federal facilities. Information associated with the unique identification code of the microchip is entered by a dental lab or

dentist on the DentureID.com website. This information will appear on a SmartPhone when using the DentureID.com app and holding the SmartPhone directly on the DentureID.com microchip.

The patient contact information retrieved from DentureID will greatly assist care givers to locate owners of lost dentures. In addition, information from DentureID Microchips will greatly help a dentist to identify elements of a denture in the case of repair. These elements may include: the type and color of denture base, teeth size and color, clips, attachment housings and implant components. These elements are nearly impossible to identify otherwise, so DentureID Microchips will improve the quality of patient care.

In the event that a denture is placed in view of others who are not “covered entities” under HIPAA regulations, DentureID Microchips help to improve caregiver compliance with privacy regulations because the denture patient’s name is not visible, unlike conventional denture identification methods.

C. Scientific Concepts That Form the Basis For The Device: The DentureID Microchip does not hold an electric charge. It remains inactive until energized by an NFC reader using RFID ISO 14443 (a common standard used at 13.56Mhz) that makes intimate contact. The low level of energy emitted by the reader (smart phone in NFC mode) “wakes-up” the microchip which responds with a unique serial number. The reader (smart phone) then communicates the serial number to the DentureID.com database and the database responds with information to display on the reader (smart phone).

D. Significant Physical and Performance Characteristics

i. Device Design – The device design is a standard RFID ISO 14443 which enables NFC communication at very short (< 1cm) distances.

ii. Material Used - The microchip is not powered and does not emit any radiation. The following is a list of materials and components used to make DentureID Microchips:

1) Microchip: Chip #NTAG213 – Manufactured by NXP. This chip is RFID ISO 14443 standard that uses NFC (near-field communication).
2) Very thin copper wire
3) Clear film printed with the words “DENTUREID.COM”
4) Medical-Grade Epoxy: LOCTITE® M-31CL™

iii. Physical Properties - The DentureID Microchip emits no energy. It responds to a 13.56Mhz transponder (smart phone and other readers) which emits approximately 40 microwatts (10-6 watts). According to the physical properties data sheet for the LOCTITE M-31CL (primary contents by mass), the Physical Properties are as follows:

Glass Transition Temperature, ASTM E 228, °C	70
Elongation, ASTM D 638, %	8
Tensile Strength, ASTM D 638 N/mm²	55.2 (psi) (8,000)

E. Duration and Type of Contact: DentureID Microchip does not contact the patient. It is embedded into a denture and completely covered with self-cure PMMA repair resin. Dentures are rarely worn 24-hours per day. They mostly removed during sleep.

F. User Procedure: The current standard of care for denture fabrication begins with a dental professional (dentist, denturist, prosthodontist) providing an impression or model and information about the case, generally including the patient's name, to a dental laboratory. The dental professional and dental laboratory are currently bound by confidentiality regulations and are "covered entities" as defined by HIPAA. When using a DentureID Microchip, the dental laboratory will fabricate the denture, insert the DentureID Microchip (dental laboratory technicians are generally familiar with denture base acrylics) and enter key information about the denture, including patient name (if provided by the dental professional), into a secure server which requires a username and password. After data entry, the dental laboratory will verify the information was entered correctly by reading the DentureID Microchip with a reader (smart phone).

The dental laboratory keeps one of the 3-part adhesive labels and adheres it to their documentation about the case which they presently safeguard per HIPAA regulations. The lab sends the other two adhesive labels with the dental prosthetic appliance to the dental professional. The dentist will keep one label with the clinical documentation on the case and give the other adhesive label to the patient. The dentist copy has space for the patient to sign and acknowledge that they are consenting to place information on DentureID.com website (consent is required part of HIPAA[1]). The dental professional, laboratory or patient may edit or remove information stored on the DentureID website. If the username or password is lost, the dentist and dental laboratory will have a record of the username and password. See section 13, Proposed Labeling, for more information and Directions for Use.

G. Model Numbers: The model number D1EN is the English version with denture branding. Future models will be other languages and branding for other appliances such as mouthguards and retainers.

H. Software - Reader: The person reading the DentureID Microchip embedded into a denture will likely use a smart phone such as an Android capable of NFC communication. The user must first download the DentureID app for Android smart phone from the Google Play store. Apple has NFC on their most modern phones for use with proprietary Apple systems such as ApplePay. Apple is planning to release NFC on their phones to developers for new applications, such as DentureID Microchip.

I. Software - Web Server: Data about the denture is entered into and maintained by a secure server hosted by Amazon. There are many healthcare organization who use the same services, including The Centers for Medicare and Medicaid Services (CMS). Details about the web server:

- Operating System: Windows server 2008 R2
- Database: Microsoft SQL Server 2008 R2 Web edition
- Web Server: Internet Information Service 7
- The SQL database access is restricted through credentials
- We will purchase an SSL certificate associated with www.dentureid.com domain so

[1] 45 C.F.R. § 164.502(a

that the web app can be accessed over https instead of normal http. This will ensure the data is encrypted over the network.

J. Disease Conditions (Devices): The DentureID Microchip will assist dentists to treat patients who are:

1. Edentulous (Complete Dentures)
2. Partially Edentulous (Partial Dentures)
3. Bruxing (Night Guards)
4. Protecting Teeth During Contact Activity (Sports Guard)
5. Involved with Teeth or Jaw Alignment Therapy (Retainer, Alignment Tray)

5. Intended Use

Indication for Use: DentureID Microchip is intended to enable access to secure patient identification and device information when used with complete dentures, partial dentures and other removable oral appliances.

General Description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate: Edentulism (people with missing teeth) and people who wear removable dental appliances

Description of the patient population for which the device is intended:

Primary: Full or partially edentulous patients.

Secondary: Patients who wear bruxing (night guard) appliances and other removable appliances such as a Sports Guards, Retainers and Alignment Trays, etc.

6. Indication Statements Comparison

DentureID Microchip (K170423)	**VeriChip (DEN040007) Predicate (Primary)**	**SmartSponge (K071355) Predicate (Reference)**	**Comments**
DentureID Microchip is intended to enable access to secure patient identification and device information when used with complete dentures, partial dentures and other removable oral appliances	The VeriChip is indicated for use as a miniature, implantable microchip that is inserted into the subcutaneous tissue of the patient. **The VeriChip provides the patient a unique identification number that may be used to access a database containing the patient's identity and health information.**	The ClearCount Medical Solutions SmartSpongeTM System is indicated for use in counting and recording the number of RFID tagged surgical sponges, laparatomy sponges and towels used during surgical procedures.	The **output** portion of the indications for use for VeriChip is virtually identical to DentureID Microchip because both chips respond with a unique identification number corresponding to a patient.

7. Technological Characteristics and Substantial Equivalence

	DentureID Microchip Micro-Transponder Specifications	**VeriChip Predicate (Primary) Micro-Transponder Specifications**	**SmartSponge Predicate (Reference) Micro-Transponder Specifications**
Common Name	RFID Tag ISO 14443 micro-transponder embedded into medical grade epoxy	RFID Tag ISO 11784/85 micro-transponder	RFID Tag ISO 15693 micro-transponder embedded into medical grade epoxy and sewn into surgical sponge
FDA Classification Number	Implantable Radiofrequency Transponder System for Patient Identification and Health Information (21 CFR 880.6300)	Implantable Radiofrequency Transponder System for Patient Identification and Health Information (21 CFR 880.6300)	Surgical sponge scale (21 CFR 880.2740)
510(k) Number	K170423	DEN040007	K071355
Operating Frequency	13.56Mhz	134.2 kHz ± 3 kHz	13.56Mhz
Peak High Op. Temperature	Up to +85° C (+185° F)	Up to +180° C (+356° F)	Up to +125° C (+257° F)
Electrical Characteristics	Passive – Operates when in presence of compatible SmartPhone in NFC mode	Passive – Operates when in presence of VeriChip's "Pocket Reader"	Passive – Operates when in presence of compatible reader
Functional Performance	Read Range potential up to 50mm, but max is 5mm (≈ 0.5 in) as tested in DentureID applications using Android Smart Phone.	Read Range 63.5mm (≈ 3.0 in)	Read Range potential up to 1 to 1.5 meters (19 in to 59 in)
Write Protected	Yes	Yes	Yes
Self-Powered	No	No	No
Encapsulating Material	LOCTITE M-31CL Medical Grade Epoxy	None	LOCTITE M-31CL Medical Grade Epoxy
Tracking Device	No	No	No
Compatibility	Compatible with various polymers and materials	Compatible with various polymers and materials	Compatible with various polymers and materials
Patient Contact	Encapsulated Microchip and epoxy shell do not touch human tissue	Encapsulated Microchip does not touch patient, but outer shell does	Encapsulated Microchip does not touch patient, but epoxy shell may
Anatomical Site	Mouth	Subcutaneous	Intra-abdominal

Source of data from company literature and manufacturer of RFID micro-transponders.

Similarities between DentureID Microchip and VeriChip (Primary Predicate)

- The indications for use for DentureID Microchip are virtually the same as the Primary Predicate because both are RFID micro-transponders and they both respond with a unique identification number corresponding to a patient.
- Both micro-transponders are passive and require energy from an outside source to respond with a serial number.
- Both micro-transponders are not tracking devices and are write-protected

Similarities between DentureID and SmartSponge (Reference Predicate)

- Both are RFID micro-transponders and they both respond with a unique identification number.
- Both RFID micro-transponders are embedded into LOCTITE M-31CL Medical Grade Epoxy.

Differences between DentureID Microchip and VeriChip (Primary Predicate)

- The micro-transponders use a different ISO standard. This difference does not raise any substantial equivalence concerns because VeriChip is designed to be read from a further distance because it is under the skin and the exact location may be unknown. DentureID Microchip is visible in a denture or other appliance so it is designed for close proximity read. Because DentureID Microchip requires close proximity read (<1 cm), it nearly impossible for an unauthorized person to obtain information related to the denture. This feature makes information from DentureID Microchip more secure than VeriChip.
- The DentureID micro-transponder and epoxy encapsulating material do not touch the patient because the DFU requires covering the device with dental acrylic. However, the VeriChip encapsulated micro-transponder is located subcutaneously. This difference does not raise any substantial equivalence concerns because DentureID is not invasive by design and results in lower patient risk.

Differences between DentureID and SmartSponge (Reference Predicate)

- The micro-transponders use a different ISO standard. This difference does not raise any substantial equivalence concerns because SmartSponge is designed to be read from a further distance because they could be located in the abdomen and the exact location may be unknown or they could be located in the “out scanner bucket” grouped together. DentureID Microchip is visible in a denture or other appliance so it is designed for close proximity read.

Applicable Standards

- 10993-1; Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
- ISO 1993-5; ISO MEM Elution Using L929, Mouse Fibroblast Cell (GLP) Cytotoxicity (2009)
- ISO 1993-10; Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization
- ISO 7405 - Evaluation of biocompatibility of medical devices used in dentistry
- IEC 60601-1-2 International Medical Safety Standard 2014
- F2052-15 Standard Test Method for Measurement of Magnetically Induced Displacement Force of Medical Devices in the Magnetic Resonance Environment 2015

8. Non-Clinical Performance testing and Compliance

The following non-clinical tests were conducted to evaluate the functionality, performance, safety and substantial equivalence as suggested by FDA's guidance for industry and FDA staff titled "Class II Special Controls Guidance Document: Implantable Radiofrequency Transponder System for Patient Identification and Health Information" issued on December 10, 2004.

A. BIOCOMPATIBILITY

Description	Standard	Result
Cytotoxicity	ISO 10993-5:2009 Biological Evaluation of Medical Devices, Part 5: Tests for In Vitro Cytotoxicity	The test article scored '0' at 24, 48, and 72 ± 4 hours and is considered non-cytotoxic under the conditions of this test.
Irritation	SO 10993-10: 2010 Standard, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization	The differences in the mean test and control scores of the extract dermal observations were less than 1.0, indicating that the requirements of the ISO Intracutaneous Reactivity Test have been met by the test article.
Sensitization	The study was conducted in accordance with ISO 10993-10:2010. Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization, pp. 18-26	None of the negative control animals challenged with the control vehicles were observed with a sensitization response greater than '0'. None of the animals challenged with the test article extracts were observed with a sensitization response greater than '0'. The normal saline extract of the test material had a sensitization response of '0' under valid test conditions. The sesame oil extract of the test material had a sensitization response of '0' under valid test conditions. Under the conditions of this protocol, the test article did not elicit a sensitization response.
Chemical Characterization of Materials (Leachate)	Proprietary standards of Nelson Laboratories and	The incremental substances found in the

	ChemTech Ford Laboratories	study are presented and compared to toxicity standards for the respective materials. As a result of the study, we feel that the potential toxicity from leaching of harmful chemicals from the DentureID RFID tag is not significant.

B. INFORMATION SECURITY PROCEDURES (DESIGN AND VALIDATION) - Passed
C. SOFTWARE VALIDATION - Passed
D. MIGRATION TESTING OF IMPLANTED TRANSPONDER - Passed
E. PERFORMANCE TESTING OF IMPLANTED TRANSPONDER - Passed
F. PERFORMANCE TESTING OF INSERTER – No inserter used
G. PERFORMANCE TESTING AND HAZARD ANALYSIS OF ELECTRONIC SCANNER – Responsibility of SmartPhone manufacturer
H. ELECTROMAGNETIC COMPATIBILITY
The following tests were completed on DentureID Microchips:

Description	Standard	Result
Radiated Emissions	EN 55011:2009	Pass
Electrostatic Discharge Immunity	EN 61000-4-2:2008	Pass
Radiated Electromagnetic Field Immunity	EN 61000-4-3:2010	Pass
Magnetic Field Immunity	EN 61000-4-8:2009	Pass

In addition, the testing found no loss or corruption of the data, latency or through-put, which was coordinated with the electromagnetic compatibility (EMC) performance of the microchip, scanner and wireless data link.

I. ELECTRICAL SAFETY PERFORMANCE TESTING – The DentureID Microchip does not emit any energy, so safety performance testing is not required.
J. STERILITY – Device is not sterile
K. MAGNETIC RESONANCE IMAGING COMPATIBILITY
The following tests were completed on DentureID Microchips:

Description	Standard	Result
Magnetic Field Interactions at 3-Tesla	(ASTM) Designation: F2052-15. Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment.	The qualitatively measured torque at 3-Tesla for the DentureID was 0, no torque. As such, this device will not present an additional risk or hazard to a patient in the 3-Tesla MRI environment or less with

		regard to torque.
MRI-related heating, 1.5-Tesla and 3-Tesla	ASTM International document: American Society for Testing and Materials International, Designation F2182–11a Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging	1.5-Tesla demonstrated a maximum of 1.5°C temperature rise and the 3-T system demonstrated a 1.9°C rise. Both of these temperature rises matched the maximum background temperature rise. In conclusion, MRI 1.5 and 3 do not induce significant heating to DentureID Microchip
Artifacts at 3-Tesla	(ASTM) International Designation: F2119-07 (Reapproved 2013), Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants	The artifacts that appeared on the MR images were shown as localized signal voids (i.e., signal loss) that corresponded to the size and shape of this device. The gradient echo pulse sequence produced larger artifacts than the T1-weighted, spin echo pulse sequence for the device. The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 10-mm relative to the size and shape of this device.
Evaluation of the Effects of MRI at 1.5-Tesla and 3-Tesla on the Function of DentureID Microchip	The goal of this investigation was to determine the effects of exposing the samples of the DentureID Microchips to 1.5-Tesla/64-MHz and 3-Tesla MRI conditions and pulse sequences selected to be representative of typical clinical MRI techniques in order to determine if these devices were damaged or if there was a change in function.	DentureID Micochips performed 100% pre and post exposures.

L. LABELING - Provided

ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process: This standard has been addressed in Section 16.

ISO 7405 Dentistry – Evaluation of biocompatibility of medical devices used in dentistry: This standard has been addressed in Section 16.

An additional non-clinical performance test was performed outside of the scope of the FDA Guidance Document. DentureID Microchips installed in dentures per DFU were subject to 5-year simulated wear with a denture cleaning medium and denture brush. The results indicated that the clear self-cure dental acrylic placed over the DentureID Microchip was not affected by the scrubbing action. Therefore, cleaning dentures will not impact the performance of DentureID Microchip.

9. Conclusions

The DentureID Microchip is substantially equivalent to VeriChip because the technology is functionally the same and the output portion of the indications for use for VeriChip is virtually identical to DentureID Microchip. Benchtop testing proved compliance with FDA's guidance for industry and FDA staff. Because DentureID is not inserted into patients, DentureID Microchip presents significantly less patient risk than VeriChip. DentureID Microchip is more effective and performs better than the predicate device, VeriChip, because:

1. DentureID Microchip does not require a specialized reader
2. After reading a Denture ID Microchip, the information returned to the reader is robust and detailed compared to VeriChip which returns only two rows of 15 character alpha-numeric strings.

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ISO 13485:2003

510(k) Summary
for
DentureID Microchip
K170423/S001

1. Applicant

Submitter's Name: Devon Howe

Date Summary Prepared: Revised August 7, 2017

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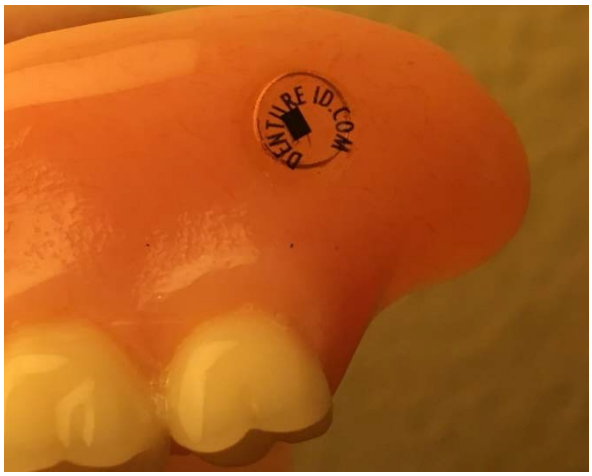

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A. Overview: DentureID Microchip enables access to secure patent identification and device information when used with removable oral appliances. Denture identification is required by many US state governments because dentures are frequently lost. DentureID.com complies with these regulations by discreetly using a microchip instead of a visible patient name. The microchip is permanently embedded into a denture and is a digital link to owner contact information and information about the denture in the event that a repair or replacement is needed. All of the information is controlled on the secure DentureID.com website by the denture owner and dental professional. This information could be important to identify and contact the owner if a denture is found. Also, if a denture requires repair, this information will be extremely valuable to a dentist or denturist who must match the size and color of denture teeth, denture base or implant/attachment components. The DentureID Microchip can be read by any NFC compatible Android Smart Phone (after downloading the DentureID.com App from Google Play) and holding the phone against the microchip. The information on the DentureID.com website may be modified at any time by the patient or dental professional by entering a username and password. The information that is on the website will appear on the smart phone when reading the DentureID Microchip.
The DentureID Microchip is not a tracking system so it will not help in finding a lost denture. It is passive and does not emit any signal until powered by a compatible Smart Phone using NFC (near field communication).

B. Explanation of How the Device Functions: DentureID Microchips are classified as RFID ISO 14443 which use NFC (near-field-communication). DentureID Microchips are designed to be read by ISO 14443 NFC-compliant smart phones with DentureID App installed. A password is not required to read the microchip, however, intimate contact between the smart phone and the microchip is required. The NFC-compliant smart phone emits a low level of energy which “activates” the DentureID Microchip when placed within intimate contact. The DentureID Microchip responds to the SmartPhone with its serial number. The SmartPhone then requests the information associated with the microchip serial number stored on the DentureID website. The website returns the stored information and displays it on the SmartPhone. Because there is no significant patient risk if the App malfunctions, this App is not considered a “Mobile Medical App.”

DentureID Microchips are encased in a medical-grade epoxy resin. The size is 1.5mm X 6 mm in diameter. They are inserted into the buccal flange of a denture and completely covered with self-cure repair resin. The DentureID Microchip does not directly contact the patient. The process to insert the microchip into a denture is performed with lower labor cost as compared to conventional denture identification methods, and it satisfies denture identification regulations required in 27 US States and federal facilities. Information associated with the unique identification code of the microchip is entered by a dental lab or

dentist on the DentureID.com website. This information will appear on a SmartPhone when using the DentureID.com app and holding the SmartPhone directly on the DentureID.com microchip.

The patient contact information retrieved from DentureID will greatly assist care givers to locate owners of lost dentures. In addition, information from DentureID Microchips will greatly help a dentist to identify elements of a denture in the case of repair. These elements may include: the type and color of denture base, teeth size and color, clips, attachment housings and implant components. These elements are nearly impossible to identify otherwise, so DentureID Microchips will improve the quality of patient care.

In the event that a denture is placed in view of others who are not “covered entities” under HIPAA regulations, DentureID Microchips help to improve caregiver compliance with privacy regulations because the denture patient’s name is not visible, unlike conventional denture identification methods.

C. Scientific Concepts That Form the Basis For The Device: The DentureID Microchip does not hold an electric charge. It remains inactive until energized by an NFC reader using RFID ISO 14443 (a common standard used at 13.56Mhz) that makes intimate contact. The low level of energy emitted by the reader (smart phone in NFC mode) “wakes-up” the microchip which responds with a unique serial number. The reader (smart phone) then communicates the serial number to the DentureID.com database and the database responds with information to display on the reader (smart phone).

D. Significant Physical and Performance Characteristics

i. Device Design – The device design is a standard RFID ISO 14443 which enables NFC communication at very short (< 1cm) distances.

ii. Material Used - The microchip is not powered and does not emit any radiation. The following is a list of materials and components used to make DentureID Microchips:

1) Microchip: Chip #NTAG213 – Manufactured by NXP. This chip is RFID ISO 14443 standard that uses NFC (near-field communication).
2) Very thin copper wire
3) Clear film printed with the words “DENTUREID.COM”
4) Medical-Grade Epoxy: LOCTITE® M-31CL™

iii. Physical Properties - The DentureID Microchip emits no energy. It responds to a 13.56Mhz transponder (smart phone and other readers) which emits approximately 40 microwatts (10-6 watts). According to the physical properties data sheet for the LOCTITE M-31CL (primary contents by mass), the Physical Properties are as follows:

Glass Transition Temperature, ASTM E 228, °C 70
Elongation, ASTM D 638, % 8
Tensile Strength, ASTM D 638 N/mm² 55.2 (psi) (8,000)

E. Duration and Type of Contact: DentureID Microchip does not contact the patient. It is embedded into a denture and completely covered with self-cure PMMA repair resin. Dentures are rarely worn 24-hours per day. They mostly removed during sleep.

F. User Procedure: The current standard of care for denture fabrication begins with a dental professional (dentist, denturist, prosthodontist) providing an impression or model and information about the case, generally including the patient's name, to a dental laboratory. The dental professional and dental laboratory are currently bound by confidentiality regulations and are "covered entities" as defined by HIPAA. When using a DentureID Microchip, the dental laboratory will fabricate the denture, insert the DentureID Microchip (dental laboratory technicians are generally familiar with denture base acrylics) and enter key information about the denture, including patient name (if provided by the dental professional), into a secure server which requires a username and password. After data entry, the dental laboratory will verify the information was entered correctly by reading the DentureID Microchip with a reader (smart phone).

The dental laboratory keeps one of the 3-part adhesive labels and adheres it to their documentation about the case which they presently safeguard per HIPAA regulations. The lab sends the other two adhesive labels with the dental prosthetic appliance to the dental professional. The dentist will keep one label with the clinical documentation on the case and give the other adhesive label to the patient. The dentist copy has space for the patient to sign and acknowledge that they are consenting to place information on DentureID.com website (consent is required part of HIPAA[1]). The dental professional, laboratory or patient may edit or remove information stored on the DentureID website. If the username or password is lost, the dentist and dental laboratory will have a record of the username and password. See section 13, Proposed Labeling, for more information and Directions for Use.

G. Model Numbers: The model number D1EN is the English version with denture branding. Future models will be other languages and branding for other appliances such as mouthguards and retainers.

H. Software - Reader: The person reading the DentureID Microchip embedded into a denture will likely use a smart phone such as an Android capable of NFC communication. The user must first download the DentureID app for Android smart phone from the Google Play store. Apple has NFC on their most modern phones for use with proprietary Apple systems such as ApplePay. Apple is planning to release NFC on their phones to developers for new applications, such as DentureID Microchip.

I. Software - Web Server: Data about the denture is entered into and maintained by a secure server hosted by Amazon. There are many healthcare organization who use the same services, including The Centers for Medicare and Medicaid Services (CMS). Details about the web server:

- Operating System: Windows server 2008 R2
- Database: Microsoft SQL Server 2008 R2 Web edition
- Web Server: Internet Information Service 7
- The SQL database access is restricted through credentials
- We will purchase an SSL certificate associated with www.dentureid.com domain so

[1] 45 C.F.R. § 164.502(a

that the web app can be accessed over https instead of normal http. This will ensure the data is encrypted over the network.

J. Disease Conditions (Devices): The DentureID Microchip will assist dentists to treat patients who are:

1. Edentulous (Complete Dentures)
2. Partially Edentulous (Partial Dentures)
3. Bruxing (Night Guards)
4. Protecting Teeth During Contact Activity (Sports Guard)
5. Involved with Teeth or Jaw Alignment Therapy (Retainer, Alignment Tray)

5. Intended Use

Indication for Use: DentureID Microchip is intended to enable access to secure patient identification and device information when used with complete dentures, partial dentures and other removable oral appliances.

General Description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate: Edentulism (people with missing teeth) and people who wear removable dental appliances

Description of the patient population for which the device is intended:

Primary: Full or partially edentulous patients.

Secondary: Patients who wear bruxing (night guard) appliances and other removable appliances such as a Sports Guards, Retainers and Alignment Trays, etc.

6. Indication Statements Comparison

DentureID Microchip (K170423)	**VeriChip (DEN040007) Predicate (Primary)**	**SmartSponge (K071355) Predicate (Reference)**	**Comments**
DentureID Microchip is intended to enable access to secure patient identification and device information when used with complete dentures, partial dentures and other removable oral appliances	The VeriChip is indicated for use as a miniature, implantable microchip that is inserted into the subcutaneous tissue of the patient. **The VeriChip provides the patient a unique identification number that may be used to access a database containing the patient's identity and health information.**	The ClearCount Medical Solutions SmartSpongeTM System is indicated for use in counting and recording the number of RFID tagged surgical sponges, laparatomy sponges and towels used during surgical procedures.	The **output** portion of the indications for use for VeriChip is virtually identical to DentureID Microchip because both chips respond with a unique identification number corresponding to a patient.

7. Technological Characteristics and Substantial Equivalence

	DentureID Microchip Micro-Transponder Specifications	**VeriChip Predicate (Primary) Micro-Transponder Specifications**	**SmartSponge Predicate (Reference) Micro-Transponder Specifications**
Common Name	RFID Tag ISO 14443 micro-transponder embedded into medical grade epoxy	RFID Tag ISO 11784/85 micro-transponder	RFID Tag ISO 15693 micro-transponder embedded into medical grade epoxy and sewn into surgical sponge
FDA Classification Number	Implantable Radiofrequency Transponder System for Patient Identification and Health Information (21 CFR 880.6300)	Implantable Radiofrequency Transponder System for Patient Identification and Health Information (21 CFR 880.6300)	Surgical sponge scale (21 CFR 880.2740)
510(k) Number	K170423	DEN040007	K071355
Operating Frequency	13.56Mhz	134.2 kHz ± 3 kHz	13.56Mhz
Peak High Op. Temperature	Up to +85° C (+185° F)	Up to +180° C (+356° F)	Up to +125° C (+257° F)
Electrical Characteristics	Passive – Operates when in presence of compatible SmartPhone in NFC mode	Passive – Operates when in presence of VeriChip's "Pocket Reader"	Passive – Operates when in presence of compatible reader
Functional Performance	Read Range potential up to 50mm, but max is 5mm (≈ 0.5 in) as tested in DentureID applications using Android Smart Phone.	Read Range 63.5mm (≈ 3.0 in)	Read Range potential up to 1 to 1.5 meters (19 in to 59 in)
Write Protected	Yes	Yes	Yes
Self-Powered	No	No	No
Encapsulating Material	LOCTITE M-31CL Medical Grade Epoxy	None	LOCTITE M-31CL Medical Grade Epoxy
Tracking Device	No	No	No
Compatibility	Compatible with various polymers and materials	Compatible with various polymers and materials	Compatible with various polymers and materials
Patient Contact	Encapsulated Microchip and epoxy shell do not touch human tissue	Encapsulated Microchip does not touch patient, but outer shell does	Encapsulated Microchip does not touch patient, but epoxy shell may
Anatomical Site	Mouth	Subcutaneous	Intra-abdominal

Source of data from company literature and manufacturer of RFID micro-transponders.

Similarities between DentureID Microchip and VeriChip (Primary Predicate)

- The indications for use for DentureID Microchip are virtually the same as the Primary Predicate because both are RFID micro-transponders and they both respond with a unique identification number corresponding to a patient.
- Both micro-transponders are passive and require energy from an outside source to respond with a serial number.
- Both micro-transponders are not tracking devices and are write-protected

Similarities between DentureID and SmartSponge (Reference Predicate)

- Both are RFID micro-transponders and they both respond with a unique identification number.
- Both RFID micro-transponders are embedded into LOCTITE M-31CL Medical Grade Epoxy.

Differences between DentureID Microchip and VeriChip (Primary Predicate)

- The micro-transponders use a different ISO standard. This difference does not raise any substantial equivalence concerns because VeriChip is designed to be read from a further distance because it is under the skin and the exact location may be unknown. DentureID Microchip is visible in a denture or other appliance so it is designed for close proximity read. Because DentureID Microchip requires close proximity read (<1 cm), it nearly impossible for an unauthorized person to obtain information related to the denture. This feature makes information from DentureID Microchip more secure than VeriChip.
- The DentureID micro-transponder and epoxy encapsulating material do not touch the patient because the DFU requires covering the device with dental acrylic. However, the VeriChip encapsulated micro-transponder is located subcutaneously. This difference does not raise any substantial equivalence concerns because DentureID is not invasive by design and results in lower patient risk.

Differences between DentureID and SmartSponge (Reference Predicate)

- The micro-transponders use a different ISO standard. This difference does not raise any substantial equivalence concerns because SmartSponge is designed to be read from a further distance because they could be located in the abdomen and the exact location may be unknown or they could be located in the “out scanner bucket” grouped together. DentureID Microchip is visible in a denture or other appliance so it is designed for close proximity read.

Applicable Standards

- 10993-1; Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
- ISO 1993-5; ISO MEM Elution Using L929, Mouse Fibroblast Cell (GLP) Cytotoxicity (2009)
- ISO 1993-10; Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization
- ISO 7405 - Evaluation of biocompatibility of medical devices used in dentistry
- IEC 60601-1-2 International Medical Safety Standard 2014
- F2052-15 Standard Test Method for Measurement of Magnetically Induced Displacement Force of Medical Devices in the Magnetic Resonance Environment 2015

8. Non-Clinical Performance testing and Compliance

The following non-clinical tests were conducted to evaluate the functionality, performance, safety and substantial equivalence as suggested by FDA's guidance for industry and FDA staff titled "Class II Special Controls Guidance Document: Implantable Radiofrequency Transponder System for Patient Identification and Health Information" issued on December 10, 2004.

A. BIOCOMPATIBILITY

Description	Standard	Result
Cytotoxicity	ISO 10993-5:2009 Biological Evaluation of Medical Devices, Part 5: Tests for In Vitro Cytotoxicity	The test article scored '0' at 24, 48, and 72 ± 4 hours and is considered non-cytotoxic under the conditions of this test.
Irritation	SO 10993-10: 2010 Standard, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization	The differences in the mean test and control scores of the extract dermal observations were less than 1.0, indicating that the requirements of the ISO Intracutaneous Reactivity Test have been met by the test article.
Sensitization	The study was conducted in accordance with ISO 10993-10:2010. Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization, pp. 18-26	None of the negative control animals challenged with the control vehicles were observed with a sensitization response greater than '0'. None of the animals challenged with the test article extracts were observed with a sensitization response greater than '0'. The normal saline extract of the test material had a sensitization response of '0' under valid test conditions. The sesame oil extract of the test material had a sensitization response of '0' under valid test conditions. Under the conditions of this protocol, the test article did not elicit a sensitization response.
Chemical Characterization of Materials (Leachate)	Proprietary standards of Nelson Laboratories and	The incremental substances found in the

	ChemTech Ford Laboratories	study are presented and compared to toxicity standards for the respective materials. As a result of the study, we feel that the potential toxicity from leaching of harmful chemicals from the DentureID RFID tag is not significant.

B. INFORMATION SECURITY PROCEDURES (DESIGN AND VALIDATION) - Passed
C. SOFTWARE VALIDATION - Passed
D. MIGRATION TESTING OF IMPLANTED TRANSPONDER - Passed
E. PERFORMANCE TESTING OF IMPLANTED TRANSPONDER - Passed
F. PERFORMANCE TESTING OF INSERTER – No inserter used
G. PERFORMANCE TESTING AND HAZARD ANALYSIS OF ELECTRONIC SCANNER – Responsibility of SmartPhone manufacturer
H. ELECTROMAGNETIC COMPATIBILITY
The following tests were completed on DentureID Microchips:

Description	**Standard**	**Result**
Radiated Emissions	EN 55011:2009	Pass
Electrostatic Discharge Immunity	EN 61000-4-2:2008	Pass
Radiated Electromagnetic Field Immunity	EN 61000-4-3:2010	Pass
Magnetic Field Immunity	EN 61000-4-8:2009	Pass

In addition, the testing found no loss or corruption of the data, latency or through-put, which was coordinated with the electromagnetic compatibility (EMC) performance of the microchip, scanner and wireless data link.

I. ELECTRICAL SAFETY PERFORMANCE TESTING – The DentureID Microchip does not emit any energy, so safety performance testing is not required.
J. STERILITY – Device is not sterile
K. MAGNETIC RESONANCE IMAGING COMPATIBILITY
The following tests were completed on DentureID Microchips:

Description	**Standard**	**Result**
Magnetic Field Interactions at 3-Tesla	(ASTM) Designation: F2052-15. Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment.	The qualitatively measured torque at 3-Tesla for the DentureID was 0, no torque. As such, this device will not present an additional risk or hazard to a patient in the 3-Tesla MRI environment or less with

		regard to torque.
MRI-related heating, 1.5-Tesla and 3-Tesla	ASTM International document: American Society for Testing and Materials International, Designation F2182–11a Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging	1.5-Tesla demonstrated a maximum of 1.5°C temperature rise and the 3-T system demonstrated a 1.9°C rise. Both of these temperature rises matched the maximum background temperature rise. In conclusion, MRI 1.5 and 3 do not induce significant heating to DentureID Microchip
Artifacts at 3-Tesla	(ASTM) International Designation: F2119-07 (Reapproved 2013), Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants	The artifacts that appeared on the MR images were shown as localized signal voids (i.e., signal loss) that corresponded to the size and shape of this device. The gradient echo pulse sequence produced larger artifacts than the T1-weighted, spin echo pulse sequence for the device. The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 10-mm relative to the size and shape of this device.
Evaluation of the Effects of MRI at 1.5-Tesla and 3-Tesla on the Function of DentureID Microchip	The goal of this investigation was to determine the effects of exposing the samples of the DentureID Microchips to 1.5-Tesla/64-MHz and 3-Tesla MRI conditions and pulse sequences selected to be representative of typical clinical MRI techniques in order to determine if these devices were damaged or if there was a change in function.	DentureID Micochips performed 100% pre and post exposures.

L. LABELING - Provided

ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process: This standard has been addressed in Section 16.

ISO 7405 Dentistry – Evaluation of biocompatibility of medical devices used in dentistry: This standard has been addressed in Section 16.

An additional non-clinical performance test was performed outside of the scope of the FDA Guidance Document. DentureID Microchips installed in dentures per DFU were subject to 5-year simulated wear with a denture cleaning medium and denture brush. The results indicated that the clear self-cure dental acrylic placed over the DentureID Microchip was not affected by the scrubbing action. Therefore, cleaning dentures will not impact the performance of DentureID Microchip.

9. Conclusions

The DentureID Microchip is substantially equivalent to VeriChip because the technology is functionally the same and the output portion of the indications for use for VeriChip is virtually identical to DentureID Microchip. Benchtop testing proved compliance with FDA's guidance for industry and FDA staff. Because DentureID is not inserted into patients, DentureID Microchip presents significantly less patient risk than VeriChip. DentureID Microchip is more effective and performs better than the predicate device, VeriChip, because:

1. DentureID Microchip does not require a specialized reader
2. After reading a Denture ID Microchip, the information returned to the reader is robust and detailed compared to VeriChip which returns only two rows of 15 character alpha-numeric strings.