SIC invent AG
Cretia Arlene McNett
Regulatory Affairs / Procurement
Birmannsgasse 3
CH-4055 Basel
SWITZERLAND

April 5, 2018

Re: K173207
Trade/Device Name: SIC invent Dental Implant Systems
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: February 28, 2018
Received: March 8, 2018

Dear Cretia Arlene McNett:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

forTina 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173207

Device Name
SIC invent Dental Implant Systems

Indications for Use *(Describe)*

SICmax onepiece implants are intended for use during dental implantation and oromaxillofacial surgery in the bone of the upper and/or lower jaw arches. They provide support for prosthetics, such as artificial teeth, bars or bridges which restore the patient's chewing function. SICmax onepiece Implants are indicated for replacing maxillary lateral incisors and mandibular central and lateral incisors. Splinting with several implants or the residual dentition is possible. SICmax onepiece implants are also indicated for immediate loading when adequate primary stability is achieved and with appropriate occlusal loading.

SICace Implants are intended for use during dental implantation and oromaxillofacial surgery in the bone of the upper and/or lower jaw arches. They provide support for prosthetics, such as artificial teeth, bars or bridges which restore the patient's chewing function. SICace Implants are indicated for immediate loading when adequate primary stability is achieved and with appropriate occlusal loading.
- Only applicable for SICace implants with Ø 3.4 mm: Use without splinting is permissible in the anterior and premolar region. In the molar region, they must be used in rigid combination with other implants. In all cases, they may only be where loads are not extreme.

SICmax Implants are intended for use during dental implantation and oromaxillofacial surgery in the bone of the upper and/or lower jaw arches. They provide support for prosthetics, such as artificial teeth, bars or bridges which restore the patient's chewing function. SICmax Implants are indicated for immediate loading when adequate primary stability is achieved and with appropriate occlusal loading.
- Only applicable for SICmax implants with Ø 3.7 mm: Use without splinting is permissible in the anterior and premolar region. In the molar region, they must be used in rigid combination with other implants. In all cases, they may only be where loads are not extreme.

SICvantage max Implants are intended for use during dental implantation and oromaxillofacial surgery in the bone of the upper and/or lower jaw arches. They provide support for prosthetics, such as artificial teeth, bars or bridges which restore the patient's chewing function. SICvantage max Implants are indicated for immediate loading when adequate primary stability is achieved and with appropriate occlusal loading.
- Only applicable for SICvantage max implants with Ø 3.0 mm: Use without splinting is permissible in the anterior region for replacement of maxillary lateral incisors and mandibular incisors. In the premolar and molar region, they must be used in rigid combination with other implants. In all cases, they may only be where loads are not extreme.

SIC Prosthetic Components are intended for use with SIC Dental Implants for prosthetic restorations from single tooth replacements to full arch restorations with fixed or removable superstructures. SIC Prosthetic Components with a post height less than 4 mm are intended for multi-unit loaded restorations only.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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