mediCAD Hectec GmbH
% Mr. Claas-Fabian Luers
Quality Assurance Representative
Opalstrasse 54
Altdorf, Bavarian 84032
GERMANY

September 7, 2018

Re: K170702
Trade/Device Name: mediCAD 4.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: August 17, 2018
Received: August 21, 2018

Dear Mr. Luers:

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. 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 located 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.

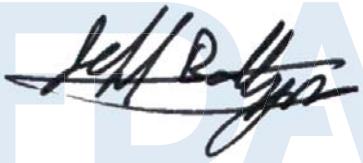
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; 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 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,



for
Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K170702

Device Name
mediCAD 4.0

Indications for Use *(Describe)*
The mediCAD classic V4.0 is a medical stand-alone software, which allows professional orthopedics preoperative measurements of existing x-rays (2D) and CT (3D). The software is intended to read in diagnostic images (e.g. digitized x-rays) from PACS-systems or conventional medias and to dimension them. An integrated database of orthopedic implant geometries can be overlayed to aid surgeons in their planning of orthopedic surgeries. mediCAD classic 4.0 can hand over the digital plannings as DICOMs to PACS-systems. Federal law restricts this device to sale by or on the order of a health professional.
mediCAD will also support the proper workflow necessary to effectively compare pre- and post-operative radiograph studies for a unique understanding of the patient's surgical outcome. Integrating this workflow with the orthopedic surgeons existing workflow and combining it with the data produced from the patient physical exam, provides a comprehensive data set for the continued prescription of a patient's relevant treatment and therapy.
The system is designed for the following medical specialties:
• Orthopedics
• Surgery and Traumatology
• Rheumatology
• Pediatric Orthopedics
MediCAD is designed for pre-operative planning for the following applications:
• Hip - Manual Planning
• Hip - Automatic Planning
• Hip - Biometry
• Hip – Intertrochanteric osteotomy
• Hip - Coxometry
• Hip - Wear Measurement
• Hip - FAI
• Knee Prosthetic Planning
• Biometry Planning –takes into account patient motion and metrics
•Coxometry – tracking of known measurement values in pediatrics to determine surgical intervention
• Osteotomy – determines optimum osteotomy locations
• Osteotomy by Dror Paley
• Osteotomy (DualSide)
• Spine
• Foot – Hallux Valgus
• Foot – Ankle Joint
• Upper Extremities
• Biological Age Determination by Hand
• Trauma
• Hip 3D
• Spine 3D

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."