



Medicrea International
% Mr. David Ryan
Chief Operating Officer
5389 Route de Strasbourg-Vancia
69140 Rillieux La Pape
FRANCE

February 8, 2018

Re: K180091

Trade/Device Name: UNiD Spine Analyzer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 4, 2018
Received: January 12, 2018

Dear Mr. Ryan:

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,



Michael D. O'Hara 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: January 31, 2017
See PRA Statement on last page

510(k) Number (if known)

K180091

Device Name

UNiD Spine Analyzer

Indications for Use (Describe)

The UNiD Spine Analyzer is intended for assisting healthcare professionals in viewing and measuring images as well as planning orthopedic surgeries. The device allows surgeons and service providers to perform generic as well as spine related measurements on images, and to plan surgical procedures. The device also includes tools for measuring anatomical components for placement of surgical implants. Clinical judgment and experience are required to properly use the software.

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

Prescription Use (Part 21 CFR 801 Subpart D)
CFR 801 Subpart C)

Over-The-Counter Use (21

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 Food and Drug
Administration
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."

510(k) SUMMARY

MEDICREA INTERNATIONAL'S UNiD SPINE ANALYZER

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted to add the UNiD Spine Analyzer.

1. Submitter:

MEDICREA INTERNATIONAL
5389 Route de Strasbourg - Vancia
69140 RILLIEUX LA PAPE
FR
Phone: +33 (0)4 72 01 87 87
Fax: +33 (0)4 72 01 87 88

Contact Person:

David RYAN
MEDICREA INTERNATIONAL
5389 Route de Strasbourg - Vancia
69140 RILLIEUX LA PAPE
FR
Phone: +33 (0)4 72 01 87 87

Date Prepared: January 04, 2018

2. Trade name: UNiD Spine Analyzer

Classification Name:

Class II, Picture archiving and communications system (21 C.F.R. 892.2050)

Classification and Regulation:

LLZ: system, image processing, radiological

3. Predicate or legally marketed devices which are substantially equivalent:

- UNiD SPINE ANALYZER (MEDICREA INTERNATIONAL, K170172) (primary predicate)
- SURGIMAP 2.0 (NEMARIS INC, K141669) (reference device)

4. Description of the new device

The purpose of this submission is to update the UNiD Spine Analyzer with the addition of a new software feature: "Data base of implants". This component will allow a user to draw implants (cages, screws and rods) taken from a range of MEDICREA INTERNATIONAL implants, previously cleared in K08009, K083810, K163595, in addition to the design of custom-made implants specific to a unique patient. A catalog of these implants is provided in this submission.

5. Indication for Use

The UNiD Spine Analyzer is intended for assisting healthcare professionals in viewing and measuring images as well as planning orthopedic surgeries. The device allows surgeons and service providers to perform generic, as well as spine related measurements on images, and to plan surgical procedures. The device also includes tools for measuring anatomical components for placement of surgical implants. Clinical judgment and experience are required to properly use the software.

6. Substantial equivalence claimed to predicate devices

The table below compares the features and technological characteristics of the cleared UNiD Spine Analyzer to the version with the updated software feature, as well as the reference Surgimap 2.0 device.

Table 1: Substantial Equivalence Comparison

Feature	UNiD Spine Analyzer with additional component	UNiD Spine Analyzer (K170172)	Surgimap 2.0 (K141669)
Computer	PC Compatible	PC Compatible	PC Compatible
Operating System	Windows + MAC	Windows + MAC	Windows + MAC
Image Input	Local	Local	Local + PACS connectivity
Runs on Server	Yes	Yes	No
Osteotomy Module	Yes	Yes	Yes
Generic measurements	Yes	Yes	Yes
Spine measurements	Yes	Yes	Yes
Pre-operative planning	Yes	Yes	Yes
Custom implants	Yes	Yes	Yes
Database	Yes (implants)	No	Yes
Case sharing	No	No	Yes
Human Intervention for interpretation and manipulation of images	Required	Required	Required
Web content	Yes	Yes	Yes

7. Non-clinical test summary

Performance data for the modified UNiD Spine Analyzer consisted of verification and validation activities. Software verification and validation testing was conducted, and documentation was provided as recommended by FDA's guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained on Medical Devices". The addition of the database of implants creates additional tools which were also tested, and documentation was provided. The software for this device was considered to be of moderate level of concern.

8. Conclusion

The addition of this new component (i.e., data base of cleared implants) to the UNiD Spine Analyzer does not raise new issues of safety or effectiveness compared to the previously cleared version of the UNiD Spine Analyzer. It is thus substantially equivalent to the company's own legally marketed predicate device.