MEDICREA International, Inc.
% Carrie Hetrick
Director of Regulatory
Sterling Medical Devices
250 Moonachie Road
MOONACHIE NJ 07074

January 12, 2022

Re: K212005
Trade/Device Name: UNiD™ Spine Analyzer
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: December 9, 2021
Received: December 10, 2021

Dear Carrie Hetrick:

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/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 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 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

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) ☐ 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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510(k) Summary

UNiD Spine

Analyzer K212005

1. **Submission Sponsor**

MEDICREA International, Inc.

5389 Route de Strasbourg - Vancia

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69140

France

2. **Submission Correspondent**

Sterling Medical Devices

250 Moonachie Road, Suite 400

Moonachie, NJ 07074

Office Phone: (201) 227-7569

Contact: Carrie Hetrick, DDS, MScRSc

Title: Director of Regulatory Affairs

3. **Date Prepared**

June 25, 2021

4. **Device Identification**

Trade/Proprietary Name:	UNiD Spine Analyzer
Common/Usual Name:	Medical Image Management and Processing System
Classification Name:	System, image processing, radiological
Regulation Number:	21 CFR §892.2050
Product Code:	LLZ

Device Class: Class II

Classification Panel: Radiology

5. Legally Marketed Predicate Device

K180091, MEDICREA International, Inc. UNiD Spine Analyzer v2.0 (primary predicate). This predicate has not been subject to a design-related recall[1]

6. Indication for Use Statement

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.

7. Device Description

The MEDICREA UNiD Spine Analyzer was developed to perform preoperative and postoperative patient image measurements and simulate preoperative planning steps for spine surgery. This web-based, Software as a Medical Device (SaMD) application aims to simulate a surgical strategy, make measurements on a patient image, and draw patient-specific rods or choose from a pre-selection of standard implants and ordering the patient-specific rods. The UNiD Spine Analyzer allows the user to:

1) Measure radiological images using generic tools and "specialty" tools

2) Plan and simulate aspects of surgical procedures

The purpose of this submission is to request clearance for the UNiD Spine Analyzer v4.0. The changes introduced are as follows:

- Addition of the Degenerative Predictive Model, which corresponds to a type of adult spinal fusion degenerative construct, trained with a retrospective longitudinal patient dataset.
- Update to the existing Adult Predictive Model consisting of three predictive model modules trained with retrospective longitudinal patient datasets, where one was included in Adult Deformity Model 1 (TKA-12) and two included in Adult Deformity Model 2 (PTA-12 and PTA-34).
- Update to the existing Pediatric Predictive Model consisting of two predictive model modules trained with retrospective longitudinal patient datasets (PediaLL and PediaPT).

[1] On July 9, 2012, section 605 of FDASIA (Pub. L. 112-144) added section 518A to the FD&C Act, which directs FDA to establish a program to routinely and systematically assess information regarding device recalls, and to use that information to proactively identify strategies for mitigating health risks presented by defective or unsafe devices. FDA believes that one way to carry out this directive is to provide greater transparency on recalled devices. Identifying whether a predicate was recalled is optional, but doing so would help the Agency achieve this FDASIA directive.

- Addition of the display of a Predicted Value derived from a static machine-learning based model when the user views simulated quantitative radiographic parameters of a planned surgery, generated when the Degenerative, Adult or Pediatric Predictive Models are used.
- The subject device update also includes the addition of a selection of implant templates among a preselected database of Medtronic standard implants cleared in in the following 510(k)s: K073291, K083026, K091813, K100175, K110543, K113528, K120368, K150135, K152277, K172199, K172328, and K201267.

8. Substantial Equivalence Discussion

The following table compares the UNiD Spine Analyzer v4.0 to the UNiD Spine Analyzer v2.0 predicate device with respect to indications for use, features, and technological characteristics.

Table 5A – Substantial Equivalence Comparison

	Subject Device **MEDICREA UNiD™ Spine Analyzer v4.0**	**Predicate Device** **MEDICREA UNiD™ Spine Analyzer v2.0**
Manufacturer	MEDICREA International, Inc.	MEDICREA International, Inc.
510(k) Number	To be determined	K180091 (Special)
Device Class	II	II
Product Code(s)	LLZ	LLZ
Regulation Description	Medical Image Management and Processing System (MIMPS)	Picture Archiving and Communication System (PACS)
Regulation Number	21 CFR §892.2050	21 CFR §892.2050
Indications 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.	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.
Computer	PC Compatible	PC Compatible
Operating System	Windows + MAC	Windows + MAC
Image Input	Local	Local

	Subject Device MEDICREA UNiD™ Spine Analyzer v4.0	Predicate Device MEDICREA UNiD™ Spine Analyzer v2.0
Runs on Server	Yes	Yes
Osteotomy Module	Yes	Yes
Generic measurements	No additional changes	The measurement panel allows a user to view the measured values of each tool. 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. Complementary to the pre-op measure, this panel also displays the simulated values and shows the normative value. Quality for the measurement is given coloring, the simulated values depending on reference values.
Spine measurements	MEASURING TOOLS: Contains all measurement tools (angle, LLordo, line, circle, pelvic, T1SPi, SVA) New features internally documented and released include SA Analysis, Sagittal wizard, Coronal wizard, Transitional anatomy, Cervical, Lenke classification, and Guide spline.	MEASURING TOOLS: Contains all measurement tools (angle, LLordo, line, circle, pelvic, T1SPi, SVA).
Pre-operative planning	SURGICAL TOOLS: Contains all surgery tools (wedge, open, resect) New features internally documented and released include wedge auto, open auto, and resect auto surgical tools.	SURGICAL TOOLS: Contains all surgery tools (wedge, open, resect).
Custom implants	IMPLANTS: Contains all implants (UNiD Rod, cage, cage selection, screw, screw selection). New features internally documented and released include UNiD Rod Auto, cage auto, screw wizard, and postop screw.	IMPLANTS: Contains all implants (UNiD Rod, cage, cage selection, screw, screw selection)
Database	Yes (implants)	Yes (implants)

	Subject Device MEDICREA UNiD™ Spine Analyzer v4.0	Predicate Device MEDICREA UNiD™ Spine Analyzer v2.0
	The subject device update also includes the addition of a selection of implant templates among a preselected database of Medtronic standard implants cleared in in the following 510(k)s: K073291, K083026, K091813, K100175, K110543, K113528, K120368, K150135, K152277, K172199, K172328, and K201267.	
Case sharing	Yes	Yes
Human intervention for interpretation and manipulation of images	Required	Required
Web content	Yes	Yes
Reference information provided to user during surgical planning	Display of reference data to user during surgery planning: Normative data Predictive model outputs from one of three predictive models, depending on procedure type (degenerative, adult deformity, pediatric deformity)	Display of reference data to user during surgery planning: Normative data

The new predictive models provide an additional tool to account for predicted spinal compensation when planning surgery; their use is similar to the display of reference and normative data, and does not raise new questions of safety and effectiveness when considered with existing methods of managing spinal compensation. Predictions are radiographic and do not include patient reported outcomes (e.g., ODI scores).

8. Non-Clinical Performance Data

The device's software development, verification, and validation have been carried out in accordance with FDA guidelines. The software was tested against the established Software Design Specifications for each of the test plans to assure the device performs as intended. The device Hazard analysis was completed per *ISO 14971, Application of Risk Management to Medical Devices* and IEC 62304, *Medical Device Software – Software Life-Cycle Processes*, and risk control implemented to mitigate identified hazards. The testing results support that all the software specifications have met the acceptance criteria of each module and interaction of processes. The MEDICREA UNiD Spine Analyzer device passed all testing and supports the claims of substantial equivalence and safe operation.

Validation activities included a usability study of the UNiD Spine Analyzer under actual use. The study demonstrated:

- Comprehension of the Health Care professional with the UNiD Spine Analyzer,
- Appropriate human factors related to the UNiD Spine Analyzer, and
- Ease of use of the UNiD Spine Analyzer.

9. Clinical Performance Data

There was no human clinical testing required to support the medical device as the indications for use is identical to the predicate device. These types of devices, including the predicate device, have been on the market for many years with proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

10. Conclusions

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise additional questions regarding its safety and effectiveness as compared to the predicate device(s).

The intended use and indications for use of the subject device is identical to the predicate device. The addition of the new features, consisting of measuring tool functionality and predictive models, to the device does not raise new issues of safety or effectiveness compared to the previously cleared versions of the device. Therefore, the UNiD Spine Analyzer v4.0 is determined to be substantially equivalent to the company's own legally marketed predicate device.