ConforMIS, Inc
Emmaniel Nyakako
Sr. Vice President, Quality and Regulatory Affairs
28 Crosby Drive
Bedford, Massachusetts 01730

Re: K170226
Trade/Device Name: iTotal Family Reusable Instrument Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: September 25, 2017
Received: September 26, 2017

Dear Emmaniel Nyakako:

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,

Michael J. Ryan -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

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 below.

510(k) Number *(if known)*
K170226

Device Name
iTotal Family Reusable Instrument Tray

Indications for Use *(Describe)*
The iTotal Family Reusable Instrument Tray is intended to house the reusable instrumentation associated with ConforMIS knee implant systems and define their organization and configuration during sterilization, transportation, and storage within the hospital environment. The iTotal Family Reusable Instrument Tray can hold up to 17lbs of instruments. The iTotal Family Reusable Instrument Tray is only intended to maintain sterility of the enclosed devices if it is used in conjunction with an FDA cleared sterilization wrap and has only been evaluated for a non-stacked configuration.

The tray is intended to allow steam sterilization of the enclosed medical devices. The validated sterilization cycle parameters are as follows:

Cycle Type: Pre-vacuum
Temperature: 132°C (270°F)
Exposure Time: 4 minutes
Dry Time: 30 minutes

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.

6.0 510(K) SUMMARY (K170226)

Submitter's Name and Address:	ConforMIS, Inc. 600 Technology Park Drive Billerica, MA 01821
Establishment Registration Number:	3009844603 and 3004153240
Date of Summary:	October 17, 2017
Contact Person:	Emmanuel O. Nyakako, Sr. Vice President, Quality and Regulatory Affairs
Telephone Number:	(781) 345-9164
Fax Number:	(781) 345-0147
Name of the Device:	iTotal® Family Reusable Instrument Tray
Common Name:	Sterilization Tray
Regulatory Status and Regulation Number:	Class II 21 CFR 880.6850
Classification Name:	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
Device Classification:	Product Code: KCT: Sterilization Wrap Containers, Trays, Cassettes & Other Accessories

510(K) SUMMARY (K170226)

Indications for Use:

The iTotal Family Reusable Instrument Tray is intended to house the ConforMIS reusable instrumentation associated with ConforMIS knee implant systems and define their organization and configuration during sterilization, transportation, and storage within the hospital environment. The iTotal Family Reusable Instrument Tray can hold up to 17lbs of instruments. The iTotal Family Reusable Instrument Tray is only intended to maintain sterility of the enclosed devices if it is used in conjunction with an FDA cleared sterilization wrap and has only been evaluated for a non-stacked configuration.

The tray is intended to allow steam sterilization of the enclosed medical devices. The validated sterilization cycle parameters are as follows:

Cycle Type	Temperature	Exposure Time	Dry Time
Pre-vacuum	132°C(270°F)	4 minutes	30 minutes

Identification of the Legally Marketed Devices (Predicate Devices):

Signia™ Sterilization Tray
Device Class: II
Product Code: KCT
Regulation Number: 21 CFR 888.6850
510(k) Number: K161347

iDrive™ Ultra Sterilization Tray
Device Class: II
Product Code: KCT
Regulation Number: 21 CFR 880.6850
510(k) Number: K130532

510(K) SUMMARY (K170226)

Device Description:

The iTotal Family Reusable Instrument Tray is a sterilization tray with perforations and brackets to hold ConforMIS knee implant reusable instrumentation. Label plates are provided to indicate where specific reusable instrumentation should be placed within the tray. The sterilization tray consists of two layers. The base layer of the tray is a full tray which includes an accessory box to hold small items. The top layer of the sterilization tray is made up of one removable tray that is ¾ the length of the overall tray and a second removable tray that is ¼ the length of the overall tray. A lid is provided with the tray and is equipped with handles to allow the user to carry the tray. The tray may contain the following instruments:

- Keel punches (not to exceed 6 per load)
- Patella clamp (not to exceed 1 per load)
- Angel wing resection guide (not to exceed 1 per load)
- Alignment rod tapers (not to exceed 2 per load)
- Drill bits and adaptors (not to exceed 6 per load)
- Coring tool with adaptors (not to exceed 1 per load)
- Pin puller (not to exceed 1 per load)
- Impactor handles, heads, and tips (not to exceed 5 per load)
- Townley caliper (not to exceed 1 per load)
- Patellar osteotomy guide (not to exceed 1 per load)
- Patella trials (not to exceed 5 per load)
- Patella sizers (not to exceed 5 per load)
- Guidance plugs (not to exceed 2 per load)
- Steinman pins (not to exceed 7 per load)
- Tack pins (not to exceed 3 per load)

The ConforMIS iTotal Family Reusable Instrument Tray is similar to the following cleared devices:

- Signia™ sterilization tray (K161347)
- iDrive™ Ultra sterilization tray (K130532)

Summary of Technological Characteristics:

The iTotal Family Reusable Instrument Tray is designed to withstand the indicated cleaning and sterilization conditions to aid in storage and sterilization of the iTotal knee accessories. The tray itself is made primarily of aluminum and doesn't require any special storage conditions. Repeated processing according to the instructions for use has been shown to have minimal effect on the sterilization tray.

510(K) SUMMARY (PAGE 4 OF 4)

Device Comparison Discussion:

The iTotal Family Reusable Instrument Tray, subject of this premarket notification, is similar to the predicate devices: Signia™ Sterilization Tray (**K161347,** cleared September 7, 2016), and iDrive™ Ultra Sterilization Tray (**K130532**, cleared May 20, 2013). Non-clinical testing was conducted to confirm that the iTotal Family Reusable Instrument Tray is similar to the predicates.

Specifically, the following testing was performed to establish similarity:

- Cleaning and Disinfection Validation
- Sterilization and Dry Time Validation
- Shelf Life Testing
- Reprocessing Fatigue Simulation

All testing has demonstrated that the device is similar to the predicate devices.

A detailed comparison of the subject device with the predicate sterilization trays is provided in the following Device Comparison Section of this document.

DEVICE COMPARISON

Table: Device Comparison Table

<table>
<tr><th>Characteristic</th><th>iTotal Family Reusable Instrument Tray (This submission)</th><th>Signia™ sterilization tray (K161347)</th><th>iDrive™ Ultra sterilization tray (K130532)</th></tr>
<tr><td>Indication for Use</td><td>The iTotal Family Reusable Instrument Tray is intended to house the ConforMIS reusable instrumentation associated with ConforMIS knee implant systems and define their organization and configuration during sterilization, transportation, and storage within the hospital environment. The iTotal Family Reusable Instrument Tray can hold up to 17lbs of instruments. The iTotal Family Reusable Instrument Tray is only intended to maintain sterility of the enclosed devices if it is used in conjunction with an FDA cleared sterilization wrap and has only been evaluated for a non-stacked configuration.

The tray is intended to allow steam sterilization of the enclosed medical devices. The validated sterilization cycle parameters are as follows:

<table><tr><td>Cycle Type</td><td>Pre-vacuum</td></tr><tr><td>Temperature</td><td>132°C (270°F)</td></tr><tr><td>Exposure</td><td>4 minutes</td></tr><tr><td>Dry Time</td><td>30 minutes</td></tr></table></td><td>The Signia™ sterilization tray is intended to provide storage for the Signia™ adapters, Signia™ reusable insertion guide and Signia™ manual retraction tool during sterilization, storage and transportation within the hospital environment. The Signia™ sterilization tray is only intended to maintain sterility of the enclosed devices if it is used in conjunction with an FDA cleared sterilization wrap and has only been evaluated for a non-stacked configuration. The tray can contain at a maximum: one (1) Signia™ adapter, one (1) Signia™ reusable insertion guide and one (1) Signia™ manual retraction tool. The tray is intended to allow steam sterilization of the enclosed medical devices. The validated sterilization cycle parameters are as follows:

132 °C Pre-vacuum (HiVac) Steam Cycles
Temperature: 270 °F (132 °C)
Exposure: 4 minutes
Dry Time: 20-40 minutes

134 °C Pre-vacuum (HiVac) Steam Cycles
Temperature: 273 °F (134 °C)
Exposure: 3 minutes
Dry Time: 20-40 minutes</td><td>The iDrive™ Ultra sterilization tray, an over-the-counter, accessory, is intended to provide storage for the iDrive™ Ultra powered stapling system during sterilization, storage and transportation within the hospital environment. The tray can contain at a maximum: one (1) iDrive™ Ultra powered handle, two (2) Endo GIA™ adapters, two (2) iDrive™ battery insertion guides and one (1) iDrive™ Ultra manual adapter tool. The tray is intended to be sterilized by the following cycles:

Prevacuum Steam Cycles
132 C for 4 minutes
134 C for 3 minutes
Vacuum Dry Time: 20</td></tr>
<tr><td>Enclosed devices for sterilization</td><td>The tray may contain the following instruments:
• Keel punches (not to exceed 6 per load)
• Patella clamp (not to exceed 1 per load)
• Angel wing resection guide (not to exceed 1 per load)</td><td>The tray can contain at maximum:
One (1) Signia™ adapter,
One (1) Signia™ reusable insertion guide
And
One (1) Signia™ manual retraction tool.</td><td>The tray can contain at a maximum:
one (1) iDrive™ Ultra powered handle,
two (2) Endo GIATM adapters,
two (2) iDrive™ battery insertion guides and
one (1) iDrive™ Ultra manual adapter tool</td></tr>
</table>

Characteristic	iTotal Family Reusable Instrument Tray (This submission)	Signia™ sterilization tray (K161347)	iDrive™ Ultra sterilization tray (K130532)
	• Alignment rod tapers (not to exceed 2 per load) • Drill bits and adaptors (not to exceed 6 per load) • Coring tool with adaptors (not to exceed 1 per load) • Pin puller (not to exceed 1 per load) • Impactor handles, heads, and tips (not to exceed 5 per load) • Townley caliper (not to exceed 1 per load) • Patellar osteotomy guide (not to exceed 1 per load) • Patella trials (not to exceed 5 per load) • Patella sizers (not to exceed 5 per load) • Guidance plugs (not to exceed 2 per load) • Steinman pins (not to exceed 7 per load) • Tack pins (not to exceed 3 per load)		
Dimensions	Base layer of the tray: 20.59" (L) X 9.84" (W) X 13.32" (H) Accessory Box: 6.000" (L) X 2.500" (W) X 1.200" (H)	Approx. 10.0 x 21.4 x 3.0 (H) inches	Approx. 10 x 21x 3 (H)
Sterilization methods	Pre-vacuum steam	Pre-vacuum steam	Pre-vacuum steam
Steam Sterilization Parameters	Cycle Type: Pre-vacuum Temperature: 132°C (270°F) Exposure: 4 minutes Dry Time: 30 minutes	Pre-vacuum (HiVac) Steam Cycles Temperature: 132°C (270°F) Exposure: 4 minutes Dry Time: 20 – 40 minutes	Prevacuum Steam Cycles 132 C for 4 minutes 134 C for 3 minutes Vacuum Dry Time: 20
Base & Lid Materials	Trays and accessory box: Aluminum Tray Lid: Radel R5000 Base Inserts (Grommets) – Silicone Medical Grade Class 6	Stainless Steel	Base – Aluminum Lid- Aluminum Base Inserts (Grommets) – Silicone Medical Grade Class 6

Characteristic	iTotal Family Reusable Instrument Tray (This submission)	Signia™ sterilization tray (K161347)	iDrive™ Ultra sterilization tray (K130532)
Stacking	Do not stack trays in the autoclave chamber. Stacking of trays will adversely affect sterilization and drying effectiveness.	Do not stack cases and trays in the sterilization chamber.	Do not stack cases and trays in the sterilization chamber. Stacking of cases and trays will adversely affect sterilization and drying effectiveness.
Max. Load Capacity	17 pounds	10 pounds	15 pounds
SAV/Hole Pattern	The ratio of total surface area of openings to volume (SAV) is: 52.3 in^2/641.7 in^3 (excluding accessory caddy). Accessory Box: Evenly distributed hole pattern	Evenly distributed hole pattern	Evenly distributed hole pattern
Product Code	KCT	KCT	KCT
Sterilant Penetration	Yes	Yes	Yes
Microbial Barrier Properties	For use with an FDA cleared wrap	For use with an FDA cleared wrap	For use with an FDA cleared wrap
Material Compatibility with Sterilization Method	Yes	Yes	Yes

Conclusion: Based upon the supporting data above, the subject device iTotal® Family Reusable Instrument Tray (K170226) is as safe and effective as the legally marketed devices Signia™ Sterilization Tray (**K161347)** and iDrive™ Ultra Sterilization Tray (**K130532**).