



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
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September 11, 2017

J. Morita USA, Inc.  
% Keith A. Barritt  
Attorney  
Fish & Richardson P.C.  
901 15<sup>th</sup> Street, N.W., Suite 700  
Washington, District of Columbia 20005

Re: K170275  
Trade/Device Name: Tri Auto ZX2  
Regulation Number: 21 CFR 872.4200  
Regulation Name: Dental Handpiece and Accessories  
Regulatory Class: Class I  
Product Code: EKX, LQY  
Dated: July 27, 2017  
Received: July 28, 2017

Dear Keith A. Barritt:

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,

**Andrew I. Steen -S**

for Lori A. Wiggins, MPT, CLT  
Acting Director  
Division of Anesthesiology,  
General Hospital, Respiratory,  
Infection Control, and Dental Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use Statement

510(K) Number : K170275

Device Name: Tri Auto ZX2.

### Indications for Use:

The Tri Auto ZX2 device is a cordless endodontic treatment motorized handpiece with root canal measurement capability. It can be used to enlarge canals while monitoring the position of the file tip inside the canal. It can be used as a low-speed motorized handpiece and device for measuring canal length.

Prescription Use

AND/OR

~~Over-The-Counter Use~~

(Part21CFR801 Subpart D)

~~(Part21CFR807 Subpart C)~~

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign-Off)

Division of Anesthesiology, General Hospital,

Infection Control, Dental Devices

510(K) Number : \_\_\_\_\_

Prescription Use   x  

or

Over-The-Counter Use

(Part21CFR801.109)

(Optional Format 1-2-96)

**510(k) Summary**  
**J. Morita USA Inc.**  
**Tri Auto ZX2**  
**Endodontic Treatment Motorized Handpiece**

The following information is provided pursuant to 21 CFR 807.92.

**807.92(a)(1): Submitter's Name/Address, Contact, and Preparation Date**

**(i) 510(k) Submitter**

J. Morita USA, Inc.  
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Phone: (949) 581-9600  
FDA Reg. No.: 2081055

**(ii) 510(k) Submitter Contact**

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**(iii) Preparation Date**

September 11, 2017

**807.92(a)(2): Name of Device**

|                            |                                                                      |
|----------------------------|----------------------------------------------------------------------|
| Trade or Proprietary Name: | Tri Auto ZX2                                                         |
| Model Name:                | TR-ZX2                                                               |
| Common Name:               | endodontic treatment motorized handpiece/<br>root canal apex locator |
| Classification Name:       | dental handpiece and accessories                                     |
| Primary Product Code:      | EKX                                                                  |
| Secondary Product Code:    | LQY                                                                  |
| Regulation:                | 21 CFR 872.4200                                                      |

### **807.92(a)(3): Predicate Devices**

The Tri Auto ZX2 (also referred to by its model number TR-ZX2) is substantially equivalent for purposes of FDA medical device regulations to various predicates. The primary predicate device is J. Morita's own Tri Auto ZX (K#970339). J. Morita's own Tri Auto Mini (K#112665) is a reference predicate for the function of enlarging root canals in particular. J. Morita's own DENTAPORT ZX (K#031204) and J. Morita's own Root ZX (K#953867 and K#921979) are reference predicates for the function of root canal measurement in particular. J. Morita's own Tri Auto Mini (K#112665), Root ZX Mini (K#090925), and DENTAPORT ZX (K#031204) are reference predicates for biocompatibility.

The Indications for Use statements for the subject device, primary predicate, and reference predicate devices (where applicable) appear below:

|                            |                                                                                                                                                                                                                                                                                                                                  |
|----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Subject Device             | The Tri Auto ZX2 device is a cordless endodontic treatment motorized handpiece with root canal measurement capability. It can be used to enlarge canals while monitoring the position of the file tip inside the canal. It can be used as a low-speed motorized handpiece and device for measuring canal length.                 |
| K#970339 primary predicate | The Tri Auto-ZX device is a cordless endodontic treatment motorized handpiece with root canal measurement capability. It can be used to enlarge canals while monitoring the position of the file tip inside the canal. It can be used to measure the length of the canal, and it can be used as a low-speed motorized handpiece. |
| K#112665                   | The Tri Auto mini motorized handpiece can be used to enlarge and prepare root canals, remove gutta-percha points, and for professional tooth cleaning. When connected to Apex locator, the Tri Auto mini can be used to measure the length of root canals.                                                                       |
| K#031204                   | The DENTAPORT ZX is a dental root canal measurement and treatment device that can measure the length of the root canal and enlarge the canal while monitoring the position of the file tip inside the canal.                                                                                                                     |
| K#090925                   | RCM-7 is a dental device, Apex Locator. It can be used to detect the apex of root canal.                                                                                                                                                                                                                                         |
| K#921979                   | Cleared prior to requirement for formal Indications for Use statements                                                                                                                                                                                                                                                           |
| K#953867                   | Cleared prior to requirement for formal Indications for Use statements                                                                                                                                                                                                                                                           |

#### **807.92(a)(4): Device Description**

The Tri Auto ZX2 is a battery-driven handpiece with a motor, equipped with a chuck for holding rotary instruments such as a dental file and reamer. The Tri Auto ZX2 can be used for cutting and grinding teeth by transferring rotary movement to a rotary instrument attached to the head. Cutting and grinding of teeth can be done depending on the situation by switching (reversing) the rotation direction. Rotation speed is accelerated or decelerated according to the user's preference, rotation control based on torque detection, or set timing. These controls enable the cutting, grinding, enlargement, and preparation of root canals. Moreover, the Tri Auto ZX2 can be used for the removal of extraneous materials such as gutta-percha points, and for professional mechanical tooth cleaning.

In addition, the Tri Auto ZX2 can be used as an apex locator, and the measured value can be used for rotation control.

The Tri Auto ZX2 is intended to be sterilized prior to use.

#### **807.92(a)(5): Indication for Use**

The Tri Auto ZX2 device is a cordless endodontic treatment motorized handpiece with root canal measurement capability. It can be used to enlarge canals while monitoring the position of the file tip inside the canal. It can be used as a low-speed motorized handpiece and device for measuring canal length.

#### **807.92(a)(6): Technological Characteristics**

The Tri Auto ZX2 device utilizes the same materials as predicate devices and the same energy source as the Tri Auto mini reference predicate device. The design is slightly different than the primary predicate device, as the Tri Auto ZX2 device is a larger sized device, but the basic design principles are the same.

The Tri Auto ZX3 device is substantially equivalent to the declared predicate devices. As noted above, the Indications for Use of TR-ZX2 device is nearly verbatim identical to the Indications for Use for the primary predicate.

A comparison table of the technological characteristics of the Tri Auto ZX2 and the predicate devices appears below:

|                              |                                                                                                                                                                                                                                                                                                                  | Primary predicate                                                                                                                                                                                                                                                                                                                | Reference predicate                                                                                                                                                                                                                                         | Similarities/Differences                                                                                                                                                                                                                                                                                                                                                                                  |
|------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product name                 | Tri Auto ZX2                                                                                                                                                                                                                                                                                                     | Tri Auto ZX                                                                                                                                                                                                                                                                                                                      | Tri Auto mini                                                                                                                                                                                                                                               | -                                                                                                                                                                                                                                                                                                                                                                                                         |
| Model                        | TR-ZX2                                                                                                                                                                                                                                                                                                           | TR-ZX                                                                                                                                                                                                                                                                                                                            | TR-CM                                                                                                                                                                                                                                                       | -                                                                                                                                                                                                                                                                                                                                                                                                         |
| Manufacturer                 | J. MORITA MFG. CORP.                                                                                                                                                                                                                                                                                             | J. MORITA MFG. CORP.                                                                                                                                                                                                                                                                                                             | J.MORITA MFG.CORP                                                                                                                                                                                                                                           | Identical                                                                                                                                                                                                                                                                                                                                                                                                 |
| 510(k) Number                |                                                                                                                                                                                                                                                                                                                  | K970339                                                                                                                                                                                                                                                                                                                          | K112665                                                                                                                                                                                                                                                     | -                                                                                                                                                                                                                                                                                                                                                                                                         |
| Intended use                 | <ul style="list-style-type: none"> <li>- Canal enlargement</li> <li>- Root canal length measurement</li> </ul>                                                                                                                                                                                                   | <ul style="list-style-type: none"> <li>- Canal enlargement</li> <li>- Root canal length measurement</li> </ul>                                                                                                                                                                                                                   | <ul style="list-style-type: none"> <li>- Canal enlargement</li> <li>- Root canal length measurement(When connected to Apex locator)</li> </ul>                                                                                                              | Intended use of Tri Auto ZX2 is the same as that of the primary predicate, Tri Auto ZX                                                                                                                                                                                                                                                                                                                    |
| Indications for use          | The Tri Auto ZX2 device is a cordless endodontic treatment motorized handpiece with root canal measurement capability. It can be used to enlarge canals while monitoring the position of the file tip inside the canal. It can be used as a low-speed motorized handpiece and device for measuring canal length. | The TRI AUTO ZX device is a cordless endodontic treatment motorized handpiece with root canal measurement capability. It can be used to enlarge canals while monitoring the position of the file tip inside the canal. It can be used to measure the length of the canal, and it can be used as a low speed motorized handpiece. | The Tri Auto mini motorized handpiece can be used to enlarge and prepare root canals, remove gutta- percha points, and for professional tooth cleaning. When connected to Apex locator, the Tri Auto mini can be used to measure the length of root canals. | <p>The Tri Auto ZX2 and Tri Auto ZX Indications for Use are nearly identical and the small difference in wording is not significant.</p> <p>The Tri Auto mini is a root canal enlargement device without the root canal measurement function. However, the Tri Auto mini can be connected to the apex locator, and it can have the same function as Tri Auto ZX2 by connecting with the Apex locator.</p> |
| Target population            | Patient population is age 12 and older                                                                                                                                                                                                                                                                           | All patients in dentistry                                                                                                                                                                                                                                                                                                        | All patients in dentistry                                                                                                                                                                                                                                   | Target population in the Tri Auto ZX2 is included in that of the predicate devices, thus, this difference has no influence on safety and effectiveness.                                                                                                                                                                                                                                                   |
| Anatomical sites             | Root canal, softened dentin                                                                                                                                                                                                                                                                                      | Root canal, softened dentin                                                                                                                                                                                                                                                                                                      | Root canal, softened dentin                                                                                                                                                                                                                                 | Identical to predicate devices.                                                                                                                                                                                                                                                                                                                                                                           |
| Where used                   | Dental clinic, University hospital and the other clinical settings                                                                                                                                                                                                                                               | Dental clinic, University hospital and the other clinical settings                                                                                                                                                                                                                                                               | Dental clinic, University hospital and the other clinical settings                                                                                                                                                                                          | Identical to predicate devices.                                                                                                                                                                                                                                                                                                                                                                           |
| Energy used and/or delivered | Li-ion battery (DC 3.7V)                                                                                                                                                                                                                                                                                         | Ni-MH battery (DC 3.6V)                                                                                                                                                                                                                                                                                                          | Li-ion battery (DC 3.7V)                                                                                                                                                                                                                                    | Energy used is the same as that of the Tri Auto mini.                                                                                                                                                                                                                                                                                                                                                     |

|                                   |                                                                                  | Primary predicate                                                                | Reference predicate                                       | Similarities/Differences                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-----------------------------------|----------------------------------------------------------------------------------|----------------------------------------------------------------------------------|-----------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product name                      | Tri Auto ZX2                                                                     | Tri Auto ZX                                                                      | Tri Auto mini                                             | -                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Model                             | TR-ZX2                                                                           | TR-ZX                                                                            | TR-CM                                                     | -                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Design                            | 30 mm x 30mm x 200 mm<br>Charger: 85 mm x 85mm x 75 mm                           | 30 mm x 37 mm x 55 mm<br>Charger: 80 mm x 123 mm x 55 mm                         | 18 mm x 18 mm x 165 mm<br>Charger: 85 mm x 108 mm x 68 mm | The exterior design of the Tri Auto ZX2 compared to the Tri Auto ZX has slightly changed for design improvement. However, the structures of both devices which include the contra angle that connects and rotates the files, the probe for measuring the root canal length, and the built-in root canal length measurement function are substantially equivalent. Moreover, the principle of controlling the rotation by measurement result, load value, setting etc. is also substantially equivalent. |
| Performance 1 - canal enlargement | 100-1,000rpm, 4Ncm (min.)                                                        | 280rpm, 4.5Ncm (min.)                                                            | 50-1,000rpm, 4Ncm (min.)                                  | The rotation speed of Tri Auto ZX2 is within the speed of the Tri Auto mini reference predicate device, thus substantially equivalent.                                                                                                                                                                                                                                                                                                                                                                  |
| Performance 2 - apex locator      | Accuracy of the root apex locator function : -1.5mm to +0.5mm for Apex position. | Accuracy of the root apex locator function : -1.5mm to +0.5mm for Apex position. |                                                           | The principle of the root canal length measurement function of the Tri Auto ZX2 is the same as the reference predicates manufactured by J. Morita (the Tri Auto ZX, DENTAPORT ZX, Root ZX and Root ZX mini). The accuracy is substantially the same.                                                                                                                                                                                                                                                    |

|                                                  |                                                                                                                                                                | Primary predicate                                                                                                                      | Reference predicate                                                                                                                    | Similarities/Differences                                                                                                                                                                                              |
|--------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product name                                     | Tri Auto ZX2                                                                                                                                                   | Tri Auto ZX                                                                                                                            | Tri Auto mini                                                                                                                          | -                                                                                                                                                                                                                     |
| Model                                            | TR-ZX2                                                                                                                                                         | TR-ZX                                                                                                                                  | TR-CM                                                                                                                                  | -                                                                                                                                                                                                                     |
| Standards met                                    | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-1-6<br>IEC 62304<br>IEC 62366<br>ISO 14971<br>ISO 10993-1<br>ISO 10993-5<br>ISO 10993-12<br>ISO 15223-1<br>ISO 17664 | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-1-4<br>IEC 60601-1-6<br>ISO 14971<br>ISO 10993-1<br>ISO 10993-5<br>ISO 10993-12<br>ISO 17664 | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-1-4<br>IEC 60601-1-6<br>ISO 14971<br>ISO 10993-1<br>ISO 10993-5<br>ISO 10993-12<br>ISO 17664 | The standards applied to the Tri Auto ZX2 include those of predicate devices, so there is no effect on safety and effectiveness.<br><br>* IEC62304 and IEC62366 are standards set after the clearance of Tri Auto ZX. |
| Materials                                        | Used materials conform to ISO10993.                                                                                                                            | Used materials conform to ISO10993.                                                                                                    | Used materials conform to ISO10993.                                                                                                    | Identical to predicate devices.                                                                                                                                                                                       |
| Spray nozzle                                     | Spray nozzle                                                                                                                                                   | Tri Auto ZX AR Spray Nozzle                                                                                                            | -                                                                                                                                      | The spray nozzle of Tri Auto ZX2 has a different shape (connection diameter is different), but its use and material are the same as for the Tri Auto ZX.                                                              |
| Compatibility with environment and other devices | Conform to IEC60601-1-2                                                                                                                                        | Conform to IEC60601-1-2                                                                                                                | Conform to IEC60601-1-2                                                                                                                | Identical to predicate devices.                                                                                                                                                                                       |
| Sterility                                        | File holder, contrary electrode, and contra Angle are autoclavable.                                                                                            | File holder, contrary electrode, and contra Angle are autoclavable.                                                                    | Contra Angle are autoclavable.<br>(File holder and Contrary electrode are not attached)                                                | Sterility is the same as that of Tri Auto ZX and there is no difference in the safety and effectiveness.                                                                                                              |
| Electrical safety                                | Conform to IEC60601-1                                                                                                                                          | Conform to IEC60601-1                                                                                                                  | Conform to IEC60601-1                                                                                                                  | Identical to predicate devices.                                                                                                                                                                                       |
| Mechanical safety                                | Conform to IEC60601-1                                                                                                                                          | Conform to IEC60601-1                                                                                                                  | Conform to IEC60601-1                                                                                                                  | Identical to predicate devices.                                                                                                                                                                                       |
| Thermal safety                                   | Conform to IEC60601-1                                                                                                                                          | Conform to IEC60601-1                                                                                                                  | Conform to IEC60601-1                                                                                                                  | Identical to predicate devices.                                                                                                                                                                                       |
| Radiation safety                                 | Conform to IEC60601-1-2                                                                                                                                        | Conform to IEC60601-1-2                                                                                                                | Conform to IEC60601-1-2                                                                                                                | Identical to predicate devices.                                                                                                                                                                                       |

### **807.92(b)(1): Non-clinical Testing**

The Tri Auto ZX2 was tested for compliance and/or developed in accordance with the following international standards, including validation of the reprocessing instructions pursuant to FDA's guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling: Guidance for Industry and Food and Drug Administration Staff":

#### IEC 60601-1 Ed.3.1:2012 Medical Electronic Equipment

This testing is designed to ensure the electrical safety of the device.

#### IEC 60601-1-2:2007 Electromagnetic Compatibility

This testing is designed to ensure the electromagnetic compatibility of the device when operated in its expected use environment.

#### IEC 60601-1-6:2010+A1:2013 Usability

This testing is designed to ensure reasonable device usability to minimize use errors and use-associated risks.

#### IEC 62304:2006 Medical Device Software

This testing is designed to ensure the software fulfils its intended purpose without causing any unacceptable risks.

#### IEC 62366 Ed.1.1 2014 Medical Devices – Application of Usability Engineering

This testing is designed to analyze, specify, design, verify and validate usability as it relates to safety of a medical device. This usability engineering process assesses and mitigates risks caused by usability problems associated with correct use and use errors, i.e. normal use.

#### ISO 14971: 2007 Application of Risk Management to Medical Devices

This standard provides a framework for systematically managing the risks associated with the use of medical devices. It addresses processes for managing risks, primarily to the patient, but also to the operator, other persons, other equipment, and the environment.

#### ISO 10993-1:2009/AC2010 Biological Evaluation of Medical Devices

This testing is designed to address the biological evaluation of medical devices within a risk management process.

#### ISO 10993-5: 2009 Biological Evaluation: Test for In Vitro Cytotoxicity

This testing is designed to assess the in vitro cytotoxicity of medical devices and to determine the biological response of mammalian cells in vitro using appropriate biological parameters.

#### ISO 10993-12:2012 Biological Evaluation: Sample Preparation and Reference Materials

This standard specifies requirements and gives guidance on the procedures to be followed in the preparation of samples and the selection of reference materials for medical device testing in biological systems.

#### ISO 15223-1:2012 Medical Devices – Symbols Used with Medical Device Labels

This standard identifies requirements for symbols used in medical device labelling that convey information on the safe and effective use of medical devices.

#### ISO 17664:2004 Sterilization of Medical Devices

#### ISO 17665-1: 2006 Sterilization of Health Care Products

#### ISO 17665-2: 2009 Sterilization of Health Care Products

This standard specifies the information to be provided by a medical device manufacturer on the processing of medical devices claimed to be resterilizable, and medical devices intended to be sterilized by the processor, so that the medical device can be processed safely and will continue to meet its performance specification. The sterility assurance level for each sterilization method was  $10^{-6}$ .

#### ISO 14457:2012 Dentistry – Handpieces and motors

This standard is applicable to handpieces and motors used in dentistry for patient contact, regardless of their construction. It specifies requirements, test methods, manufacturer's information, marking and packaging.

Performance testing was conducted to confirm that the device is capable of measuring and enlarging root canals in a manner that is substantially equivalent to the primary predicate and reference predicate devices.

Biocompatibility testing was conducted for certain materials, namely, the polyphenylsulfone (PPSU) used in the contra angle and the polypropylene used for the disposable cover.

In summary, the non-clinical testing establishes that the device is substantially equivalent.

**807.92(b)(2): Clinical Testing**

There were no clinical tests performed for the Tri Auto ZX2 device.

**807.92(b)(3): Conclusions from Testing**

Based on the comparison of the Tri Auto ZX2 device to the primary predicate device and reference predicates identified above, and based on the data gathered in the non-clinical testing described above, it is concluded that the data provided in this 510(k) submission demonstrates that the Tri Auto ZX2 device is substantially equivalent to the predicate devices.