April 24, 2023

Artiria Medical SA
Robin Stephens
Acting Head of Regulatory
Campus Biotech B3 N06
Chemin des Mines 9
Geneva, CH-1202
Switzerland

Re: K222690
Trade/Device Name: SmartGUIDE deflectable hydrophilic guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: MOF, DQX
Dated: March 22, 2023
Received: March 24, 2023

Dear Robin Stephens:

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,

Naira Muradyan -S

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K222690

Device Name
SmartGUIDE deflectable hydrophilic guidewire

Indications for Use *(Describe)*
SmartGUIDE guidewire is intended for general intravascular use, including neurovascular and peripheral vasculatures. It can be used to selectively introduce and position catheters and other interventional devices within the peripheral and neurovasculature. SmartGUIDE is intended to be used only by physicians trained in percutaneous, intravascular techniques and procedures.

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.***

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**510(k) Summary**
**SmartGUIDE deflectable hydrophilic guidewire**
**K222690**


| | |
|---|---|
| **Submission Sponsor:** | Artiria Medical SA<br>Campus Biotech B3 N06, Chemin des Mines 9,<br>Geneva CH-1202, Switzerland |
| Company Phone No.: | +41 78 649 0401 |
| Applicant Contact:<br>Email: | Mr. Guillaume Petit-Pierre<br>guillaume@artiria-medical.com |
| Correspondent Contact:<br>Email: | Mr. Robin Stephens<br>rstephens@psephos.com |


| | |
|---|---|
| **Date Prepared:** | April 20, 2023 |

**Device Identification**

| | |
|---|---|
| **Trade/Proprietary Name:** | SmartGUIDE deflectable hydrophilic guidewire |
| **Common/Usual Name:** | Catheter Guide Wire |
| **Classification Name:** | Guide, Wire, Catheter |
| **Regulation Number:** | 21 CFR 870.1330 |
| **Product Code:** | MOF, DQX |
| **Device Class:** | II |

**Predicate Device(s):**

| | |
|---|---|
| Primary predicate: | Synchro$^2$ Support Guidewire (K190843, product code MOF, DQX) |
| Predicate: | PV 2000 Synchro2 Guidewire (K053268, product code DQX) |
| Reference: | Columbus Guidewire (K200374, product code MOF, DQX) |

**Indications for Use Statement**

The Indications for Use for the SmartGUIDE deflectable hydrophilic guidewire are the same as the primary predicate Synchro$^2$ Support Guidewire and are as follows:

> SmartGUIDE guidewire is intended for general intravascular use, including neurovascular and peripheral vasculatures. It can be used to selectively introduce and position catheters and other interventional devices within the peripheral and neurovasculature. SmartGUIDE is intended to be used only by physicians trained in percutaneous, intravascular techniques and procedures.

**Device Description**

SmartGUIDE is a deflectable guidewire for general intravascular use, including neurovascular and peripheral vasculatures. It can be used to selectively introduce and position catheters and other interventional devices within the peripheral and neurovasculature. The device is available with a nominal outer diameter of 0.014'' (0.36 mm) and overall length of 200 cm. The device is available sterile and is for single use only.

**Technological Characteristics and Product Feature Comparison**

The subject device, SmartGUIDE deflectable hydrophilic guidewire is substantially equivalent to the primary predicate device in terms of:

- indications for use;
- materials;
- technological characteristics;
- packaging and sterilization of devices.

The differences in technological characteristics do not raise new questions of safety and effectiveness compared to the predicate device as outlined in the comparison table below.

| **Feature** | **Synchro$^2$ Support Guidewire Primary Predicate (K190843)** | **SmartGUIDE Subject Device (K222690)** |
|---|---|---|
| Regulation Number | 21 CFR 870.1330 | Same |
| Regulation Name | Catheter Guide Wire | Same |
| Regulatory Class | II | Same |
| Product Code | MOF, DQX | Same |
| Indications for Use | The Synchro$^2$ Guidewire series is intended for general intravascular use, including neurovascular and peripheral vasculatures. It can be used to selectively introduce and position catheters and other interventional devices within the peripheral and neurovasculature. This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures. | SmartGUIDE guidewire is intended for general intravascular use, including neurovascular and peripheral vasculatures. It can be used to selectively introduce and position catheters and other interventional devices within the peripheral and neurovasculature. SmartGUIDE is intended to be used only by physicians trained in percutaneous, intravascular techniques and procedures. |
| Target Population | The device will be used in patients undergoing endovascular treatment including neurovascular and peripheral vasculatures. | Same |
| Anatomical Sites | Peripheral and neuro vasculature | Same |
| Guidewire Diameter | 0.014” | Same |
| Core Wire | 304 Stainless Steel | 304 Stainless Steel and Nickel-Titanium |

| Feature | Synchro$^2$ Support Guidewire<br>Primary Predicate (K190843) | SmartGUIDE<br>Subject Device (K222690) |
|---|---|---|
| Core Wire Length | 215 cm Access Length<br>300 cm Exchange Length | 200 cm Access Length<br>(Same as K053268) |
| Guidewire Tip | Nickel-Titanium,<br>Micro-Machined Nitinol | Same |
| Radiopaque Coil | Platinum, 7 cm | Platinum/Iridium, 2 cm<br>(Same as K200374) |
| Adhesive | UV Curable Adhesive | Thermal Curable Adhesive |
| Primer | Parylene Dimer | No primer |
| Hydrophilic Coating (Top) | Proprietary Hydrophilic Top Coat | Proprietary Hydrophilic Top Coat |
| Hydrophilic Coating (Base) | Proprietary Hydrophilic Base Coat | Proprietary Hydrophilic Base Coat |
| Torque Device | Available commercially per K936032 | Proprietary torque device / manipulator handle supplied |
| Tip Shaping | Manual shaping of the tip prior to device delivery | In situ tip deflection mechanism, controlled by the user via the proximal end of the device<br>(Same as K200374) |
| Dispenser Hoop | High Density Polyethylene | Same |
| Sterile Pouch | Tyvek® - Polyethylene | Same |
| Shipping Carton | Solid Bleached Sulphate (SBS) | Same |
| Sterilization Method | Ethylene Oxide | Same |
| How Supplied | Sterile/Single Use | Same |

**Testing Summary**

The device passed all performance bench testing in accordance with internal requirements, referenced guidance and international standards as shown in the table below to support substantial equivalence of the device.

| Test | Standards and guidance | Results |
|---|---|---|
| Dimensional and Visual Verification | FDA Guidance for Industry and Food and Drug Administration Staff: Coronary, Peripheral, and Neurovascular Guidewires - Performance Tests and Recommended Labeling, October 2019 (thereinafter, “FDA Guidewire Guidance”) and ISO 11070 | Pass |
| Simulated Use | FDA Guidewire Guidance | Pass |
| Tip Flexibility | FDA Guidewire Guidance | Pass |
| Torqueability | FDA Guidewire Guidance | Pass |
| Kink Resistance | FDA Guidewire Guidance | Pass |
| Fracture Test | ISO 11070 | Pass |
| Flexing Test | ISO 11070 | Pass |
| Tensile Strength and Tip Pull | FDA Guidewire Guidance and ISO 11070 | Pass |
| Torque Strength | FDA Guidewire Guidance | Pass |
| Particulate Release | FDA Guidewire Guidance | Pass |
| Lubricity | FDA Guidewire Guidance | Pass |
| Coating Integrity | FDA Guidewire Guidance | Pass |
| Corrosion Resistance | FDA Guidewire Guidance and ISO 11070 | Pass |
| Radiopacity | FDA Guidewire Guidance | Pass |

In addition, specific bench tests were designed to support the subject device in situ bending mechanism. These are listed below.

| Test | Description | Results |
|---|---|---|
| Tip actuation force | The maximum tip deflection force was measured during complete deflection in a simulated vessel to verify it is within the specified range. | Pass |
| Tip fatigue | Testing was conducted to demonstrate the tip deflection mechanism durability to 30 full handle actuations. | Pass |
| Blood clot crossing | Testing was conducted to demonstrate crossing of soft and hard clots. | Pass |

**Biocompatibility**

The materials used in the manufacture of the subject device SmartGUIDE deflectable hydrophilic guidewire are of well characterized medical grade.

Biocompatibility testing was completed in accordance with ISO 10993 and consisted of the following tests:

- Cytotoxicity
- Sensitization
- Intracutaneous reactivity
- Material mediated pyrogenicity
- Bacterial endotoxins
- Acute systemic toxicity
- Complement activation
- Hemolysis
- Thrombogenicity
- EtO sterilization residuals

All tests confirmed biocompatibility.

**Sterilization and Shelf life**

The device is sterilized using Ethylene Oxide. The sterilization process has been validated in accordance with EN ISO 11135. The device is non-pyrogenic.

Testing of the device after accelerated aging (T = 2 years accelerated aging) confirmed that all acceptance criteria were met supporting the shelf-life of the device.

**Pre-Clinical Animal Testing Data**

As part of demonstrating the substantial equivalence to the predicate device, Artiria Medical completed a controlled good laboratory practice (GLP) study in domestic swine with the subject device and the predicate device. Usability, performance, subacute (3-day) and chronic (30-day) vascular safety, and thrombogenicity were assessed in this study. The following table presents an overview of the results of this study.

| **Endpoint** | **Assessed parameters** | **Results**<br>**(Subject device equivalent to predicate device)** |
|---|---|---|
| Overall, in life health | Clinical health status of animals. | Pass / Equivalent |
| Efficacy / functional evaluation | Manoeuvrability, navigability, pushability, trackability, compatibility with ancillary devices. | Pass / Equivalent |
| Procedural, Subacute, and Chronic safety | Macro- and microscopic evaluation of the treated vessels, downstream tissues, and major organs. | Pass / Equivalent |

| | | |
|---|---|---|
| Thrombogenicity | Thrombus formation at the surface of the test and control articles.<br>Fibrin deposits or thrombosis in treated arteries. Presence of non-patent artery.<br>Thrombus in distal organs. | Pass / Equivalent |

**Statement of Substantial Equivalence**

The SmartGUIDE deflectable hydrophilic guidewire has the same intended use and indications for use, and similar technological characteristics compared to the Synchro$^2$ Support Guidewire predicate device. The differences in technological characteristics do not raise different questions of safety and effectiveness compared to the predicate, and the nonclinical testing discussed above demonstrates that the subject device performs as intended. Therefore, the device is substantially equivalent to the predicate device.