June 17, 2026

Socko Medical Co., Ltd.
Ariel Huang
RA
10F-3, No. 8, Ln. 609, Sec. 5, Chongxin Rd., Sanchong Dist
New Taipei, 24159
Taiwan

Re: K253045
Trade/Device Name: "Socko" Vimax Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: May 18, 2026
Received: May 19, 2026

Dear Ariel Huang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

EILEEN CADEL -S

for

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253045

Please provide the device trade name(s).

"Socko" Vimax Spinal Fixation System

Please provide your Indications for Use below.

The "Socko" Vimax Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.
The "Socko" Vimax Spinal Fixation System can be used in a percutaneous approach. The "Socko" Vimax Spinal Fixation System is intended for noncervical pedicle fixation from T1 to S1 for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; deformities (i.e., scoliosis, kyphosis, and/or lordosis); spinal tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K253045 - 510(k) Summary

1. **Type of submission:** Traditional

2. **Date of summary:** June 17, 2026

3. **Submitter information:**

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Phone:	+886-2-2999-1288
Fax:	+886-2-2999-1287
Correspondent:	Ariel Huang (shingmissbig@gmail.com)

4. **Identification of the subject device:**

Device Name:	"Socko" Vimax Spinal Fixation System
Review Panel:	Orthopedic
Regulation Number:	21 CFR 888.3070
Regulation Description:	Thoracolumbosacral pedicle screw system
Classification Product Code:	NKB
Device Class:	Class II

5. **Identification of the primary predicate device:**

510(k) number:	K161387
Device Name:	Mont Blanc and Mont Blanc MIS Spinal Systems
Manufacturer:	Spineway S.A.
Review Panel:	Orthopedic
Regulation Number:	21 CFR 888.3070
Regulation Description:	Thoracolumbosacral pedicle screw system
Classification Product Code:	NKB
Subsequent Product Code:	OSH, MNI, MNH, KWP
Device Class:	Class II

6. **Description**

The "Socko" Vimax Spinal Fixation System is composed of implant devices made from a titanium alloy Ti6Al4V per ISO 5832-3 and ASTM F136. It is to be implanted from the posterior approach. The screws are available as Vimax MIS Fenestrated Cortical Screw (in diameters from 4.5-7.0 mm and in lengths from 25-60 mm), Vimax MIS Reduction Fenestrated Cortical Screw and Vimax LT Fenestrated Cortical Screw in

diameters from 5.0-7.0 mm and in lengths from 30-60 mm and Screw Nut of 8.7 mm diameters with height of 4.2 mm. The rods are available as Traction Pre-bend Rod in 5.5mm diameter and in lengths from 40-140 mm and Traction Rod in 5.5mm diameter and in lengths from 100-550 mm.

7. Indications for Use

The "Socko" Vimax Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.

The "Socko" Vimax Spinal Fixation System can be used in a percutaneous approach.

The "Socko" Vimax Spinal Fixation System is intended for noncervical pedicle fixation from T1 to S1 for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; deformities (i.e., scoliosis, kyphosis, and/or lordosis); spinal tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

8. Performance Data - Non-clinical Testing

We provided following non-clinical testing in accordance with the ASTM F1717-21 standard in support of the substantial equivalence determination.

- Static axial compression testing
- Static torsion testing
- Dynamic axial compression testing

We performed "Static axial compression testing" and "Static torsion testing" to verify that the compressive yield load and torsional yield torque of the construct exceed the mechanical performances of the predicate device. We performed "Dynamic axial compression testing" to verify that the construct does not experience any failure at a higher endurance load limit.

All the test results demonstrate "Socko" Vimax Spinal Fixation System is substantially equivalent to the predicate device.

9. Performance Data - Clinical Testing

No clinical test data was used to support the decision of substantial equivalence.

10. Substantial equivalence comparison

"Socko" Vimax Spinal Fixation System submitted in 510(k) files is substantially equivalent in intended use, safety and performance to the FDA cleared Mont Blanc and Mont Blanc MIS Spinal Systems (K161387). Differences between the devices cited in this section do not raise any new issue of substantial equivalence.

Item	Subject device	Predicate device	Equivalent
Proprietary name	"Socko" Vimax Spinal Fixation System	Mont Blanc and Mont Blanc MIS Spinal Systems	-
510(k) no.	K253045	K161387	-
Indications for Use	The "Socko" Vimax Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine. The "Socko" Vimax Spinal Fixation System can be used in a percutaneous approach. The "Socko" Vimax Spinal Fixation System is intended for noncervical pedicle fixation from T1 to S1 for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic	The Mont Blanc and Mont Blanc MIS Spinal Systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine and sacral/iliac screw fixation. The Mont Blanc and Mont Blanc MIS Spinal Systems are intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal	***Equivalent***

Item	Subject device	Predicate device	Equivalent
	studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; deformities (i.e., scoliosis, kyphosis, and/or lordosis); spinal tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.	stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.	
Type of Use	Prescription Use	Prescription Use	***Same***
Level of Use	T1-S1	T1-S1	***Same***
Conditions for Use	Professional use only in a professional healthcare environment.	Professional use only in a professional healthcare environment.	***Same***
Intended user	Skeletally mature patients	Skeletally mature patients and pediatric patients	***Different.*** The intended user of the subject device is narrower
Material	Titanium alloy Ti6Al4V	Titanium alloy Ti6Al4V-ELI and Cobalt-Chrome	***Equivalent.*** Both the devices have the material Ti6Al4V
Sterilization	End user sterilized	Provided sterile	***Different***
Screws	Diameters: 4.5-7.0 mm Length: 25-60 mm	Diameters: 4.0-8.0 mm Length: 25-110 mm	***Equivalent.*** The size range of subject device is equivalent with predicate device.
Rods	Diameters: 5.5 mm Length: 40-550 mm	Diameters: 5.5 mm Length: 40-500 mm	***Equivalent.*** The size range of subject device is equivalent with predicate device. The

Item	Subject device	Predicate device	Equivalent
			safety and performance test has been completed to demonstrate safety and effectiveness.

11. Conclusion

The data demonstrates that the subject device is substantially equivalent to the predicate device.