July 21, 2026

Beijing Honghugaoxiang Science and Technology Development CO
Zichen Jia
RA Specialist
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Park Daxing Biomedical Industry Base, Daxing District
Beijing, Beijing 102600
China

Re: K253814
Trade/Device Name: Raney Clips Kit
Regulation Number: 21 CFR 882.4150
Regulation Name: Scalp Clip
Regulatory Class: Class II
Product Code: HBO
Dated: July 1, 2026
Received: July 2, 2026

Dear Zichen Jia:

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,

JULIA E. SLOCOMB -S

Digitally signed by JULIA E. SLOCOMB -S
Date: 2026.07.21 15:55:15 -04'00'

for Jaime Raben, Ph.D.
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

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.	K253814

Please provide the device trade name(s).

Raney Clips Kit

Please provide your Indications for Use below.

The Raney Clips Kit is indicated for use in temporary hemostasis of the scalp edge.

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

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

510(k) Summary

1. Date of Preparation: 07/20/2026

2. Sponsor Identification

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3. Designated Submission Correspondent

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Contact Person: Zichen Jia
Position: RA Specialist
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Email: hhgxzc@hhgx.cn

4. Identification of Subject Device

Trade Name: Raney Clips Kit
Common Name: Scalp Clip and Applier

Classification Name: Clip, Scalp; Classification: II
Product Code: HBO
Regulation Number: 21 CFR 882.4150
Review Panel: Neurology

5. Identification of Predicate Device

510(k) Number: K012219
Trade Name: ScalpFix Clip System

6. Indications for Use

The Raney Clips Kit is indicated for use in temporary hemostasis of the scalp edge.

7. Device Description

The subject device, Raney Clips Kit, is indicated for use in temporary hemostasis of the scalp edge. The device is provided sterile and single use.

The subject device consists of a clip applier and cartridge(s) that is pre-loaded with scalp clips. With the pull of a trigger, the scalp clips are fired into the scalp tissue and create a squeezing force on the scalp tissue directly surrounding the bleeding vessels, causing them to constrict or close. As a result, blood flow through these vessels is greatly restricted, leading

to temporary hemostasis (stopping bleeding).

The shelf life of the subject device is three years. The subject device is sterilized by Ethylene Oxide to achieve a SAL of 10-6 and supplied in sterility maintenance package which could maintain the sterility of the device during the shelf life of 3 years.

Raney Clips Kit is available in two series with six models, HZ Sa and HZ Sb. They differ only in the number of clips and accompanying cartridges. Cartridges are available in three numbers of clips: 12,13, and 16. The clip applier, scalp clip and cartridge in each series have the same material and manufacturing process and are different only in number of cartridges. All models of the Raney Clips Kits share identical material composition, device design, sterile barrier and manufacturing process.

8. Comparison of Technological Characteristics

Table 1 General Comparison

ITEM	**Subject device**	**Predicate Device, K012219**	**Remark**
Device Name	Raney Clips Kit	SCALPFIX CLIP SYSTEM	/
Product Code	HBO	HBO	Same
Regulation No.	882.4150	882.4150	Same
Class	Class II	Class II	Same
Indication for Use	The Raney Clips Kit is indicated for use in temporary hemostasis of the scalp edge.	Aesculap's Scalpfix is indicated for use in temporary hemostasis of the scalp edge.	Same
Principle of Operation	The clip applier has a pistol-like design and holds an exchangeable, pre-loaded cartridge of scalp clips. With the pull of a trigger, the scalp clips are inserted into the scalp tissue, and grip the margin of the scalp wound tightly to provide temporary hemostasis.	Aesculap's scalp clip gun (FF012R) is used in conjunction with Aesculap's scalp clip (FF013P) to insert sterile plastic scalp clips at the margin of scalp wounds, providing temporary hemostasis of the opened scalp.	Similar
Configuration	Clip Applier Cartridge	Clip Applier Cartridge	Same
Single-use	Single-use only	Scalp Clip - Singe-use only Clip Applier - Reusable	Different
Clip Material	Polyoxymethylene (POM)	Polyoxymethylene (POM)	Same
Clip Pattern	Serrated jaw	Straight jaw	Different
Number of clips in each cartridge	12, 13, 16	10	Different
Sterile	Supplied STERILE	Scalp Clip - Supplied STERILE Clip Applier - Non-sterile	Different
Shelf life	3 Years	Scalp Clip - 5 Years Clip Applier - N/A	Different

9. Summary of Nonclinical Testing

Nonclinical tests were conducted to verify that the subject device met all design specifications and to support the Substantially Equivalent (SE) determination.

Bench testing

The bench test performed on the subject device and predicate device includes appearance, dimension, clamping force, tooth spacing and simulated use tests. The test results demonstrated that the subject device and predicate devices have similar product performance.

Package integrity

The package integrity of the subject sterility maintenance package includes visual inspection, seal strength and dye penetration resistance. The test results demonstrated that the subject device complies with the following standards:

- ASTM F88/F88M-23, Standard Test Method for Seal Strength of Flexible Barrier Materials.
- ASTM F1929-23 Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration.
- ASTM F1886/F1886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

Simulated transportation

A simulated transportation test was conducted on the subject device following the standard below. The test results demonstrate that packing can protect the device from damage during distribution environments.

- ASTM D4169-23 Standard Practice for Performance Testing of Shipping Containers and Systems

EO and ECH Residue

Examination of the Ethylene Oxide (EO) and Ethylene Chlorohydrin (ECH) residuals have been conducted in accordance with ISO 10993-7:2008. The test results demonstrated that the subject device complies with the allowable limits.

Bacterial Endotoxins

Medical device endotoxin contamination is associated with a risk of pyrogenic reactions in patients. Endotoxin limit is established as 20 USP Endotoxin Unit (EU) for the subject device. Test has been conducted by Limulus Amebocyte Lysate (LAL) method according to USP <85> Bacterial Endotoxin Limit. The test results demonstrated that the subject device complies with the allowable limits.

Shelf life

A maximum shelf life of 3 years has been assigned to the subject device. In order to ensure the safety and effectiveness of subject device in the shelf life, following testing was conducted to provide valid data for the device shelf life:

- Package integrity after simulated distribution
- Package integrity of the accelerated aging device and unaged device, Performance testing of accelerated aging device

Biocompatibility

The subject device has limited contact duration and tissue contact level, Therefore, it was tested for Cytotoxicity (ISO 10993-5), Sensitization (ISO 10993-10), Intracutaneous Reactivity (ISO 10993-23), Acute Systemic Toxicity (ISO 10993-11) and Material-mediated Pyrogenicity (ISO 10993-11 and USP <151>).

10. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject devices are as safe and effective when compared to the legally marketed predicate device K012219. The Indications for Use, technological characteristics, and performance of the proposed Raney Clips Kit are substantially equivalent to the predicate device.