July 13, 2023

Aesculap Implants Systems LLC
Hamza Ahmed
Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K231769
Trade/Device Name: activL® Next Generation Instrumentation
Regulation Number: 21 CFR 888.4515
Regulation Name: Orthopedic manual surgical instrumentation for use with total disc replacement devices
Regulatory Class: Class II
Product Code: QLQ
Dated: June 16, 2023
Received: June 16, 2023

Dear Hamza Ahmed:

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,

Brent Showalter -S

Brent Showalter, Ph.D.
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

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)*
K231769

Device Name
activL® Next Generation Instrumentation

Indications for Use *(Describe)*
The Aesculap Implant Systems® activL® Next Generation Instrumentation are indicated for the successful implantation of the Aesculap activL® device. These instruments are intended to manipulate tissue or implant materials for the positioning, alignment, defect creation, placement, or removal of the activL® device.

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.

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510(k) Summary

Device Trade Name:	activL® Next Generation Instrumentation
Manufacturer:	Aesculap Implant Systems, LLC 3773 Corporate Pkwy Center Valley, PA 18034
Contact Person:	Hamza Ahmed Specialist, Regulatory Affairs Aesculap Implant Systems, LLC 3773 Corporate Pkwy Center Valley, PA 18034 Phone: (610) 737-3900 Hamza.Ahmed@bbruanusa.com
Date Prepared:	July 12, 2023
Registration Number:	3005673311
Product Code:	QLQ
Classifications:	Class II – 21 CFR §888.4515
Classification Name:	Orthopedic manual surgical instrumentation for use with total disc replacement devices
Predicate Device(s):	Primary - K220861 M6-C Artificial Cervical Disc Instruments (Approved via PMA P170036 and reclassified in Q200722) Reference – P120024 activL Artificial Disc

Reason for the 510(k) Submission: Design Changes to activL® Trials, activL® Trial Holders, activL® Depth Stop, activL® Trial Inserter, activL® Single and Double Chisels, activL® Impaction Caps, activL® Depth Stop Driver, and activL® Implant Inserter

Device Description:

The activL® Next Generation Instrumentation would allow successful implantation of the Aesculap activL® device. These are manual surgical instruments which aid in selecting, placing, and revising the activL® device. These activL® instruments device comprises of trial, trial holders, single and double chisels, implant inserter, trial inserter, depth stop, depth stop driver, and impaction caps.

Indications for Use:

The Aesculap Implant Systems activL® Next Generation Instrumentation are indicated for the successful implantation of the Aesculap activL® device. These instruments are intended to manipulate tissue or implant materials for the positioning, alignment, defect creation, placement, or removal of the activL® device.

Performance Testing Summary:

activL® Next Generation Instrumentation have been evaluated via the following performance testing:

- Simulated use/Functional testing
- Transit testing
- Sterilization/Cleaning validation

The results demonstrated the performance of activL® Next Generation Instrumentation is substantially equivalent to the predicate devices.

Substantial Equivalence:

The subject device is substantially equivalent to the predicate devices with respect to indication, design, materials, function, and performance.

Conclusion:

activL® Next Generation Instrumentation have the same intended use, indications for use, technological characteristics as the predicate devices (K220861 / P170036 / Q200722, P120024), and the results of performance testing demonstrate the subject device do not introduce any new question of safety or effectiveness. Therefore, the activL® Next Generation Instrumentation is substantially equivalent to the cited predicate devices.