Akunah PTY LTD
Shanthan Pather
Coo
131 Warriewood St
QUEENSLAND, 4151
AUSTRALIA

May 10, 2023

Re: K222987
Trade/Device Name: Akunah REFLECT
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: April 6, 2023
Received: April 6, 2023

Dear Shanthan Pather:

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,

Jessica Lamb,
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of Radiological Health
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)*
K222987

Device Name
Akunah REFLECT

Indications for Use *(Describe)*
Akunah Reflect Planning Software is intended to be used as a pre-surgical planner for shoulder arthroplasty, fracture, deformity correction and stabilisation procedures. The software is used to assist in the positioning of shoulder components. Akunah Reflect Planning Software allows surgeons to visualize, measure, reconstruct, and annotate anatomic data. The software leads to the generation of a planning report. The software is to be used for adult patients only and should not be used for diagnostic purposes. Akunah Reflect should be used in conjunction with expert clinical judgement.

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 **K222987**

Traditional 510(k) – Akunah REFLECT
May 10th 2023

Device Name

Trade name:	Akunah REFLECT
Common Name:	Image processing system
Classification Name:	Medical image management and processing system
Regulation Number:	§892.2050

Submitter

Name:	Akunah Pty Ltd
Address:	Suite 307, Nicholson Street Specialist Centre Level 9, 121 Newdegate St, Greenslopes 4120 Brisbane, Australia

Company Contact

Contact Name:	Akunah Pty Ltd
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Classification

Device	Class: Class II
Classification Panel:	Radiology
Product Code:	QIH, LLZ

21 CFR section 892.2050, Class II Radiology Devices – Panel: Radiology
Office of Radiological Health (OHT8)

Equivalent / Predicate Device

Trade Name	510(k) number	Decision Date	Applicant
Mimics Medical **(PRIMARY PREDICATE)**	K183105	March 27, 2019	Materialise NV
BLUEPRINT™ Patient Specific Instrumentation **(REFERENCE)**	K203315	April 15, 2021	Tornier SAS
Materialise Shoulder System, Materialise Shoulder Guide and Models, SurgiCase Shoulder Planner **(REFERENCE)**	K193560	March 20, 2020	Materialise NV

Device Description

Akunah REFLECT Software is intended to be used as a pre-surgical planner for shoulder arthroplasty, fracture, deformity correction and stabilisation procedures. The user interface software is connected to an online management system (OMS), and is intended to be used by orthopaedic surgeons as a preoperative planning software for shoulder surgery. The software is intended to allow surgeons to:

- Visualize, measure, reconstruct, and annotate anatomic data,
- Select and position shoulder implant devices,
- Output pre-surgical planning reports

The software is to be used for adult patients only and should not be used for diagnostic purpose.

Intended Use

Akunah REFLECT Software is intended to be used as a medical software to assist in pre-operative surgical planning for shoulder surgery.

Indication For Use

Akunah Reflect Planning Software is intended to be used as a pre-surgical planner for shoulder arthroplasty, fracture, deformity correction and stabilisation procedures. The software is used to assist in the positioning of shoulder components. Akunah Reflect Planning Software allows surgeons to visualize, measure, reconstruct, and annotate anatomic data. The software leads to the generation of a planning report. The software is to be used for adult patients only and should not be used for diagnostic purposes. Akunah Reflect should be used in conjunction with expert clinical judgement.

Comparison to Predicate Device

Akunah Reflect has been compared to legally marketed predicate device Materialise – Mimics Medical (K183105), and references devices:- Tornier - BLUEPRINT Patient Specific Instrumentation (K203315), and Materialise – Surgicase Shoulder Planner (K212569). The predicate device shares the same intended use for the software, specific to treatment planning for surgical procedures, allowing visualisation, reconstruction, measurements, annotations and editing of anatomic data. To achieve these features Akunah REFLECT employs similar fundamental technologies as the predicates.

The following technological differences exists between the subject device and the predicates:

- Akunah REFLECT does not offer a hardware component – Patient Specific Guide (PSI) or Anatomic Models, as it is a software-only device
- Akunah REFLECT possess a unique user interface to optimise workflow and user experience.

The differences outlined above do not raise new questions of safety and effectiveness over the predicate device as demonstrated in verification and validation testing.

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Performance Data

Software verification and validation testing were performed, and documentation provided as per the *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (2005).* Verification testing was performed to address all functional requirements, and usability testing was performed to demonstrate overall validation of the software against the user needs.

- Akunah REFLECT met the acceptance criteria stated for all functional verification testing across all systems and modules.
- Geometric accuracy of the virtual models created in the subject device were assessed. Both Akunah Auto-segmentation and Premorbid Reconstruction demonstrated equivalent accuracy as established by the predicate devices.
- Measurement Tools were verified to achieve an acceptable accuracy
- Usability testing demonstrated the validation of the software on the Desktop for surgical planning

In conclusion, all performance testing conducted demonstrated device performance and substantial equivalence to the predicate device.

Substantial Equivalence Conclusion

The results of the verification and validation testing raise no concerns regarding the safety and effectiveness of the product. Minor differences in the non-fundamental technological characteristics raise no question of safety and effectiveness of the software. Performance data support the demonstration of substantial equivalence and usability. Therefore, the intended use, fundamental technological characteristics, and principle of operation of the Akunah REFLECT software are substantially equivalent to the predicate device.

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