February 2, 2023

Atomica Technology, Inc.
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

Re: K230012
Trade/Device Name: Atomica Planner
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: December 30, 2022
Received: January 3, 2023

Dear Prithul Bom:

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,

Lu Jiang 2023.02.02 14:29:07 -05'00'

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems 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

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below

Indications for Use

510(k) Number *(if known)*

K230012

Device Name

Atomica Planner

Indications for Use *(Describe)*

"Atomica Planner" is stand-alone software indicated for use by highly qualified dental professionals in the preoperative simulation-based planning of implant placements, and designing patients' 3D model surgical guides to support dental treatment surgeries (such as teeth replacement for Adult patients with missing/damaged teeth; taking into account dental functional & esthetic aspects).
"Atomica Planner" image-processing functions & tools provide users with 2D/3D visualization & segmentation for imported medical digital imaging (DICOM) datasets (acquired originally by optical/medical scanners, such as CT) to enhance the image-guided detection of suitable implant placements based on the evaluation of intraoral surrounding tissue. System users can also export patient plan dataset output with final surgical instructions PDF report, and the designed surgical guide 3D models in the imaging (STL) file format which is compatible with a wide range of 3rd parties manufacturing systems.

“Atomica Planner” system is intended to be used only by highly-qualified dental professionals with sufficient training in implantology & surgical dentistry as well as practical experience with using digital imaging technologies and in an environment suitable for reading diagnostic dental DICOM data sets.

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.

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K230012

Introduction

This document is a Summary of descriptive information about the similarities & differences between the New "Atomica Planner" Device and the Predicate Device in terms of the intended use/purpose, safety, effectiveness, and functional performance characteristics. Besides, benefits, Hazards, and adverse safety information.
Note: Each (Blue texted) title/word in this document links to its related (FDA 21 CFR) regulatory reference page.

1. The Submitter Information

Company Name:	Atomica Technology, Inc
Company Address:	6445 Powers Ferry RD NW Atlanta, GA 30339 United States
Company Phone:	+1 415-275-0302
Contact Person - Position:	Mr. Yahia Megahed – CEO
Summary preparation Date:	February 1, 2023

2. New Device

Device Trade Name:	**Atomica Planner**
Common/Usual Name:	Atomica 3D Dental Implants
Classification Name:	Medical Image Management and Processing System
Regulation Number:	892.2050
Regulatory Class:	Class II
Classification Product Code:	LLZ
Regulation Medical Specialty:	Radiology

3. Predicate Device

Trade Name/Product Name:	**3Shape Implant Studio**
510(k) Number:	K202256
Manufacturer:	3Shape Medical A/S
Regulatory Class:	Class II
Device Classification Name:	System, Image Processing, Radiological
Regulation Number:	892.2050
Classification Product Code:	LLZ
Regulation Medical Specialty:	Radiology

4. Device Description

- "Atomica Planner" is a standalone desktop application intended for pre-operative simulation-based planning of implant placements & dental surgical treatments (such as teeth replacement for Adult patients with missing/damaged teeth; taking into account dental functional & esthetic aspects).
- The system is intended to be used only by well-trained and highly qualified dental professionals, based mainly on medical digital image processing functions & tools (2D/3D visualization & segmentation).
- A project file is created from the patient's imported medical imaging (DICOM) dataset (generated originally by medical/optical scanners, such as CT) to support dental professionals in the implant placements detection and suitable sleeves/drills types selection according to the image-guided anatomical measurements/evaluations of (surrounding/adjacent roots & nerves, available bone mass/density, and variations in maxilla & mandible).
- System users can export their plan dataset outputs with final surgical instructions PDF report, and the designed surgical guide 3D models in the imaging (STL) file format which is compatible with a wide range of manufacturing systems.

- The software is designed to run on standard "PC" platforms that meet the identified minimum (SW/HW) requirements and the environment of use of the device is the "Professional Healthcare Facility".
- Results produced by "Atomica Planner"software's visualization-based diagnosis & planning tools for dental implant treatments are mainly dependent on the interpretation of qualified & well-trained dental professionals.
- "Atomica Planner" is a stand-alone software medical device and does not contact the human body, nor does it directly control or integrate with any physical or digital life-sustaining medical devices.

4.1. (Hardware/Software) Environment - Minimum Requirements:

Having an adequate computer system is essential for using the "Atomica Planner" software application efficiently and generating the highest quality images possible. The most important element is the video card (3D graphics chip or GPU). To ensure proper operation and full utilization of all the software features, we recommend the following (HW/SW) environment configurations or higher:

Item	Specifications
CPU/Processor	Quad-Core and 2.8 GHz
System Memory/RAM	8 GB
Graphics	Dedicated GPU with at least 4 GB video RAM or better
Monitor Resolution	1080p (1920x1080), if a DPI setting of 100% is used. (If you use a higher DPI setting, a higher resolution is required).
Platform/OS	Windows (10/11 64-Bit) - Linux – Mac

4.2. "Atomica Planner" Software Major Functionalities:

System Module/ Feature	Description
DICOM Import-Module	This module is responsible for receiving DICOM datasets and maintaining the data included in the dataset header. User moves to the folder where the DICOM images are copied. The images from DICOM files are selected and previewed to be added to a treatment plan generated by the software. The loaded dental DICOM images (obtained from the dental imaging machine).
Plan Creation Module	This module is responsible for selecting the specific ROI (region of interest) from the DICOM dataset and specific HU (Hounsfield Units) range to generate the desired 3D object.
Segmentation Module	This module enables the user to segment 3D image to separate objects and remove undesired parts, eliminate scattering effect and undesired anatomy. It provides the possibility to create separate models or 3D view of maxilla, mandible, teeth or prosthesis.
Panoramic Module	This module facilitates the drawing of user defined curved surfaces that offers an essential advantage to display specific structures to acquire an initial impression from the anatomy.
Nerve Module	This module allows the user to track the mandibular - alveolar canal (which will be clearly shown on the panoramic image) to simulate the mandibular nerves passing through alveolar canal.
Model Module	This module allows for the visualization and manipulation of the optical surface scan data (Cross sectional , Axial, Tangential, Centric, MPR)
Implant Module	This module is responsible for preparing and placing implants in the correct position and visualizing its relationship with other objects (nerves, bone, and teeth).
Reporting Module	The module allows for the generation and export of planning data reports including the particular positions, orientations and type of implants and drill sleeves to be used in the surgical procedures.
Export Module	The module allows for exporting of the 3D models. Surgical guides can be manufactured using the exported data when used as input to 3D manufacturing systems.

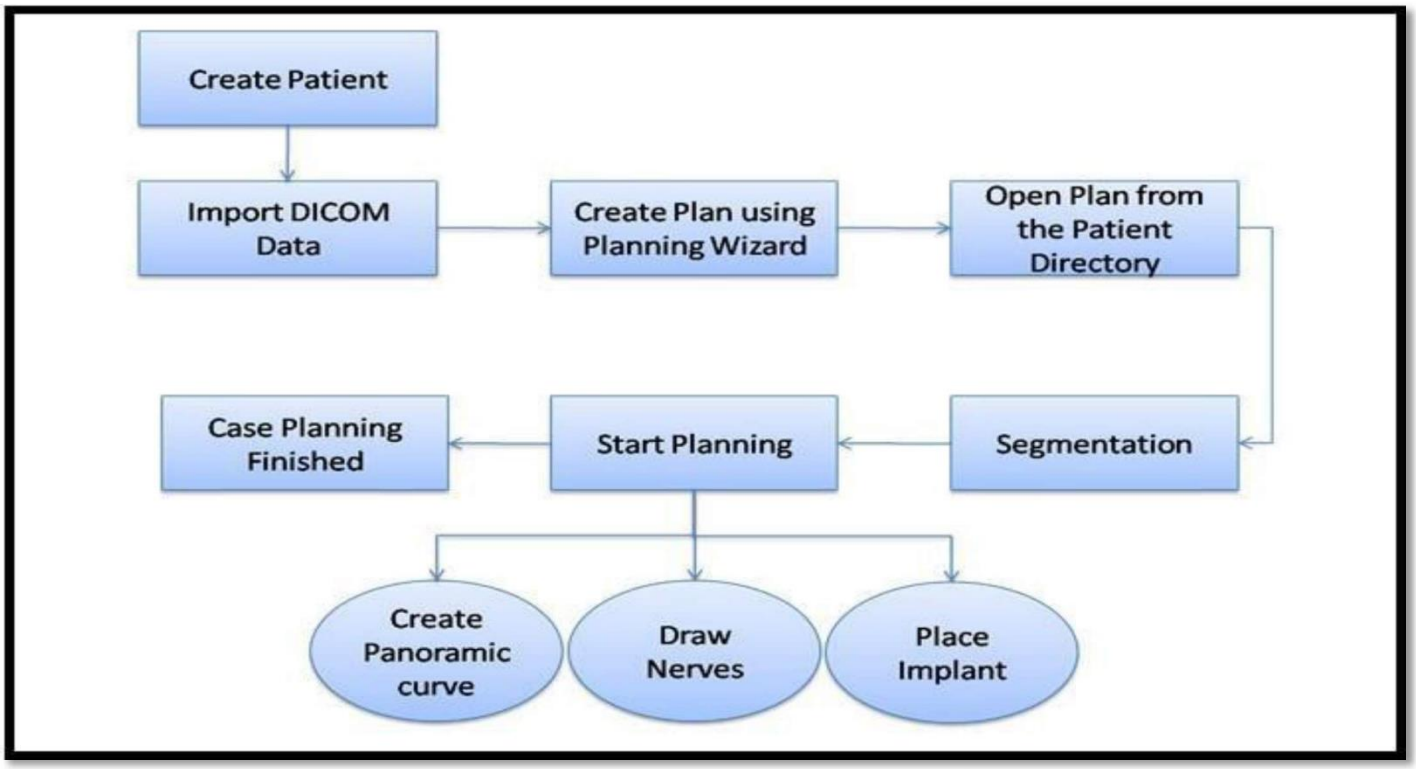

Figure-1 – Atomica Planner System Modules – Workflow

4.3. Software Principles of Operations/Mechanism: **[Visualize, Plan, Measure, Implant, Save & Export]**

- The "Atomica Planner" software Principles of functional Operations and the Mechanism of the system design workflow based mainly on applying software image manipulation & processing methods/techniques, such as 2D/3D visualization & segmentation tools on patients' imported medical digital imaging files (DICOM) dataset (generated initially for the patient case from a medical scanner, such as CT). The system integrates the optical scan data with (CT) enabling accurate digital planning for implant placements and surgical guides' 3D designing for implementation of the implantology plan.
- Amongst imaging data, geometric and mathematical information, practical information such as acquisition details and settings are included in the DICOM file, which means more efficiency & safety from intraoperative mistakes.
- Viewing Tools: To reveal different anatomical structures (e.g. nerves, roots, bone thickness & density...etc.) the system provides users with viewing tools that provide the ability to rotate, zoom, pan, change window width & window level of the rendered images. Also provides (coronal, sagittal, centric, cross sectional, panoramic, 3D) supported views to allow dental professionals view the case from different perspectives, and detect critical needed measurements, such as (dimensions of implants, sleeves, distance from adjacent teeth, distance & angles between implants, depth, inner/outer diameters, and tooth occlusal angle).
- The 2D views are created using the Multi-planner reconstruction process, which uses the data from the axial CT image to create non axial 2D images. It is the process of creating sections or cuts through a volumetric dataset. The 3D image (volume) is reconstructed by stacking DICOM images (slices) with no superimposition of anatomical structures and no magnification. It is the most standardized method for visualization of 3D dataset or the method of choice for initial inspection.
- Measurement tools: Useful tools for dental professionals to detect & evaluate critical data required for developing an effective implants placement plan (e.g. dimensions of implants, sleeves, distance from adjacent teeth, distance & angles between implants, depth, inner/outer diameters, bone thickness & density, and tooth occlusal angle..., etc.)
- Save & Export: Dental professionals can save a plan of a clinical case. The saved plan can be used later for reviewing or editing on it or sharing with other dental professionals by exporting plan dataset outputs with final surgical instructions PDF report, and the designed surgical guide 3D models in the imaging (STL) file format which is compatible with a wide range of manufacturing systems.

4.4. Software Scientific Concept:

- Using 3D surface imaging system in virtual planning for dental implant surgeries and diagnosis based on (DICOM) datasets that contain the (CT/CBCT) image files and other patient-related information (patient name, ID number, etc.).
- Dental professionals/surgeons need to use the software application to determine implant placements according to the ideal position and the available bone volume to eliminate possible manual placement errors. Integrating the optical scan data with (CBCT) datasets enables accurate digital planning for implant placements and surgical guide's fabrication for precise implementation of that plan, which means more efficiency & safety from any intraoperative mistake.
- The ability to import intraoral and dental impressions or optical scan data models into CT-support computer software applications with a user-friendly human-computer interaction graphical interface such as "Atomica Planner" device which also has the ability to overlay and transfer 2D data to 3D digital imaging & communications in medicine (DICOM) datasets; can provide implantology professionals with safe & simple image processing techniques for computer-aided dental implant surgical treatment pre-planning, besides improving the precision while placing implants in a minimally invasive manner.

4.5. Software Performance Characteristics:

- Minimum amount of memory depends on the size of the data sets being processed (number of DICOM image slices loaded plus the image width and height) so far the optimum and recommended memory amount is (8 GBs).
- Two main factors affect the GPU (Graphics Processing Unit) specification: number of streaming processors and the size amount of GPU memory. [Recommended amount of memory is 512 MB at least for the GPU].
- The performance of "Atomica Planner" depends on the quality and accuracy of the CBCT /CT that have been imported into the software. [The system user is solely responsible to ensure that the quality of the data imported in the software is sufficient for the proper performance of "Atomica Planner". The DICOM data from CBCT or CT devices should have a resolution of at least 512x512 and a slice width of ≦1 mm. There shall be no artifacts and distortions in the regions of interest so that relevant anatomical structures are visible in the scans].
- The implant placement is determined by measuring the distance and angle of adjacent teeth using digital imaging simulations functions & 3D design models of surgical guides. Determining the implant placement by measuring the distance and angle of adjacent teeth, roots, nerves, and bone density)
- The system provides users with different views to place points located on the course of the nerve. When user wants to end the course, user double clicks on the last point. Software then connects all points forming a tabular form line representing the course of the nerve. [Nerve default diameter is 2.00 mm, and user can change it from settings area].
- In order to maintain the performance of the application, the user is recommended to select case specific ROI & HU values, from which 3D object is created showing the anatomical structure or tissues falling within this (HU range & ROI). Hounsfield unit (HU) scale is a linear transformation of the original linear attenuation coefficient measurement; it is defined as zero Hounsfield units (HU), while the radio density of air at STP is defined as -1000 HU. Dental professionals use this scale to differentiate between different tissues during diagnosis.
- (Cross sectional) view is a sagittal cut along the panoramic curve. User draws a panoramic curve then a cross sectional line is drawn by default. Three cross sectional images are drawn by default, with 2.00 mm. spacing between them. Three representative lines for the cross sectional images are placed on the panoramic curve in the axial view.
- The system allows users to change the slab thickness using a spin box showing the current thickness and "up" and "down" buttons. Changing slab thickness occurs with 2.00 mm. lab. Panoramic image is updated after the change in the runtime.
- Data shown in the generated panoramic image should reflect the data in the course of the panoramic curve and number of slices superimposed in the slice thickness.

4.6. Patient Safety - General Considerations:

- The success in realizing the exact match in expected results of the preoperative implant virtual plan doesn't do not only depends on the accuracy of evaluated placement measures but depends basically on the health condition of the mouth tissues, gingiva, mucous membranes, and jaws, as well as the shape, size, and position of the bones of the jaws, adjacent & opposing, and also the expected amount of stress that will be put on the implants and fixtures during its normal function.
- There are health conditions that preclude starting a plan for placing implants, and some cases that can increase the implant failure risk: (heavy smokers, diabetics, and patients with bone diseases).

4.7. "Atomica Planner" Safety Precautions:

- The system user must learn how to perform measurements correctly & employ proper usage of all measurement tools. Any incorrect measurement can lead to surgical complications if diagnosis, treatment plans, and actual treatment are based on incorrect measurements.
- For maximum utilization of the Atomica Planner Software, users should read the "Atomica Planner" software user guide and follow technical instructions for achieving highly accurate results.
- Due to the nature of medical imaging, the boundary is not always well defined; the apparent boundary depends on the current brightness and contrast setting. The boundary may shift as the system user makes adjustments to brightness and contrast, and end-users must understand the limitation of the measurement value before applying it to the patient.
- The Software does not contain any guarantee if the real-life implementation of the faulty virtual treatment planning might result in harm to the patient. BUT it is very important for dental professionals to verify that imported & exported data sets are of adequate quality and match the patient's anatomical structures.
- To make the best final decision for the patient's dental implant surgery. The "Atomic Planner" software medical device's user should not primarily rely only on the virtual plan dataset or its final report's information & recommendation that have been provided by the system. All virtual treatment plans should be evaluated by a well-trained licensed implantology professional, confirming that the virtual treatment can be implemented in real life and will not cause harm to the patient.

5. Intended Use/Indications For Use (IFU)

"Atomica Planner" is stand-alone software indicated for use by highly qualified dental professionals in the preoperative simulation-based planning of implant placements, and designing patients' 3D model surgical guides to support dental treatment surgeries (such as teeth replacement for Adult patients with missing/damaged teeth; taking into account dental functional & esthetic aspects).
"Atomica Planner" image-processing functions & tools provide users with 2D/3D visualization & segmentation for imported medical digital imaging (DICOM) datasets (acquired originally by optical/medical scanners, such as CT) to enhance the image-guided detection of suitable implant placements based on the evaluation of intraoral surrounding tissue. System users can also export patient plan dataset output with final surgical instructions PDF report, and the designed surgical guide 3D models in the imaging (STL) file format which is compatible with a wide range of 3rd parties manufacturing systems.
"Atomica Planner" system is intended to be used only by highly-qualified dental professionals with sufficient training in implantology & surgical dentistry as well as practical experience with using digital imaging technologies and in an environment suitable for reading diagnostic dental DICOM data sets.

5.1. Intended Users Profile Characteristics/Persona:

The software device intended to be used only by highly-qualified dental professionals with sufficient training in implantology & surgical dentistry, as well as practical experience with using digital imaging technologies; in environment suitable for reading diagnostic dental DICOM datasets.

5.2. Intended Patient Population & Medical Conditions:

"Adult Patients" who have intra-oral defects (e.g. a missing/damaged single tooth or several missing teeth in multiple areas) are the type of patient populationfor which the "Atomica Planner" software device is intended to aid qualified dental professionals in preoperatively planning their implant treatment surgeries (e.g. replacing single/multiple teeth).
Note: Adults are considered 22 years old and greater. § 814.3(s)

5.3. Indication Statements Equivalence:

Subject Device: "Atomica Planner"	Predicate Device: "3Shape Implant Studio" K202256
Indication for Use: "Atomica Planner" is stand-alone software indicated for use by highly qualified dental professionals in the preoperative simulation-based planning of implant placements, and designing patients' 3D model surgical guides to support dental treatment surgeries (such as teeth replacement for Adult patients with missing/damaged teeth; taking into account dental functional & esthetic aspects). "Atomica Planner" image-processing functions & tools provide users with 2D/3D visualization & segmentation for imported medical digital imaging (DICOM) datasets (acquired originally by optical/ medical scanners, such as CT) to enhance the image-guided detection of suitable implant placements based on the evaluation of intraoral surrounding tissue. System users can also export patient plan dataset output with final surgical instructions PDF report, and the designed surgical guide 3D models in the imaging (STL) file format which is compatible with a wide range of 3rd parties manufacturing systems. "Atomica Planner" system is intended to be used only by highly-qualified dental professionals with sufficient training in implantology & surgical dentistry as well as practical experience with using digital imaging technologies and in an environment suitable for reading diagnostic dental DICOM data sets.	**Indication for Use:** "3Shape Implant Studio" is an implant planning and surgery planning software tool intended for use by dental professionals who have appropriate knowledge in dental implantology and surgical dentistry. This software reads imaging information output from medical scanners such as CT and optical scanners. It allows preoperative simulation and evaluation of patient anatomy and dental implant placement. Surgical guides and the planned implant position can be exported as 3D models and the guides can be manufactured using said 3D models when used as input to 3D manufacturing systems.

§ 807.100(b)(1):

"Atomica Planner" device & the predicate device "3Shape Implant Studio" have the same "Intended us/purpose" for aiding the same "Intended Users/Persona" the qualified and well-trained dental professionals in the preoperative implant placements evaluation & planning; based on medical digital image processing technology using 2D/3D visualization of imported CT images from (DICOM) datasets. Moreover, both devices have a similar functional mechanism for designing surgical guide 3D models exported to a 3rd party manufacturing device.

6. Technological Characteristics Comparison – Subject Device .vs Predicate Device

Comparable Criteria	New Device	Predicate Device	Evaluation
Device Name / 510(k) #	**"Atomica Planner"**	**"3Shape Implant Studio"** K202256	-
FDA Classification	- Class II - 21 CFR 892.2050 - Medical Image Management and Processing System - LLZ	- Class II - 21 CFR 892.2050 - System, Image processing, Radiological - LLZ	**Equivalent**
Description & Principles of Operations	A standalone desktop application intended for pre-operative simulation-based planning of implant placements & dental surgical treatments (such as teeth replacement for Adult patients with missing/damaged teeth; taking into account dental functional & esthetic aspects). The system is intended to be used only by well-trained and highly qualified dental professionals, based mainly on medical digital image processing functions & tools (2D/3D visualization & segmentation). A project file is created from the patient's imported medical imaging (DICOM) dataset (generated originally by medical/optical scanners, such as CT) to support dental professionals in the implant placements detection and suitable sleeves/drills types selection according to the image-guided anatomical measurements/evaluations of (surrounding/adjacent roots & nerves, available bone mass/density, and variations in maxilla & mandible). System users can export their plan dataset outputs with final surgical instructions PDF report, and the designed surgical guide 3D models in the imaging (STL) file format which is compatible with a wide range of 3rd parties manufacturing systems.	A stand-alone software device used to pre-operatively plan the placement of a dental implant based on the visualization of a patient's CT image, optionally aligned to an optical 3D surface scan. A virtual surgical guide can be designed and then exported to an external system for manufacturing. The device has no patient contact being a software only device. The guide can be used for aiding the placement of the implant(s) to the intended position(s). PDF reports are generated to document the planning information and to provide an overview of the required surgical steps and components. The system allows visualization of an imported CT image from DICOM data to pre- operatively analyze and plan the placement of dental implant(s) in the maxilla and/or mandible region by taking the prosthetic and clinical requirements into consideration.	**Equivalent**
Input Source	Imaging files generated from: (CT/CBCT)	Imaging files generated from: (CT/CBCT)	**Equivalent**
Output Compatibility	CAD, rapid prototyping machines	CAD, rapid prototyping machines	**Equivalent**

▪ **Data Conformance**	DICOM dataset	DICOM dataset	**Equivalent** Both products use DICOM to import patient images for processing.
Purpose	Visualization and simulation that aids users in the preoperative planning for placements of dental implants and surgical treatments	Visualization and simulation that aids users in the preoperative planning for placements of dental implants and surgical treatments	**Equivalent**
User Interface	Monitor, Mouse, Keyboard	Monitor, Mouse, Keyboard	**Equivalent**
Main tools	Visualization, implant & placement, measurement of distances & angles, density determination, segmentation tool.	Visualization, implant & placement, measurement of distances & angles, density determination, segmentation tool.	**Equivalent**
Platform Compatibility	Desktop Operating Systems [Windows 10/11 (64-bit) - Mac Linux] PC / Laptop	Desktop Operating Systems [Windows 7/8/10 (64-bit)] PC / Laptop	**Equivalent**
Monitor Resolution	(1920x1080) pixels	(1920x1080) pixels	**Equivalent**
Graphical User Interface/ GUI	2D and 3D views	2D and 3D views	**Equivalent** With (Minor) differences in graphic appearance.

6.1. Major Software Functions/System Design Comparison:

Software Function/ Feature Name	"Atomica Planner"	3Shape Implant Studio	Substantial Equivalence
DICOM import	**Yes**	**Yes**	**Equivalent**
Panoramic curve	**Yes**	**Yes**	**Equivalent**
Nerve creation	**Yes**	**Yes**	**Equivalent**
Implant planning	**Yes**	**Yes**	**Equivalent**
Save & Export plan	**Yes**	**Yes**	**Equivalent**
Length measurement	**Yes**	**Yes**	**Equivalent**
Angle measurement	**Yes**	**Yes**	**Equivalent**
Manual Alignments	**Yes**	**Yes**	**Equivalent**
Segmentation	**Yes**	**Yes**	**Equivalent**
3D volume presets	**Yes**	**Yes**	**Equivalent**
Sleeve Library	**Yes**	**Yes**	**Equivalent**
Surgical Guide Design	**Yes**	**Yes**	**Equivalent**
Dentures	**-**	**Yes**	**Different** Atomica Planner doesn't have Dentures feature, which is an additional option, and raise no new safety or effectiveness questions.

6.2. Technological Similarities: 807.100(b)(2)(i)

- "Atomica Planner" device & the predicate device "3Shape Implant Studio" have the same purpose of Visualization/ Simulation of imported CT images from the (DICOM) dataset to support dental professionals in the preoperative planning for placements of dental implants and dental surgeries. Moreover, both devices have also the same mechanism of designing surgical guide 3D models which can be exported to a 3rd parties manufacturing device.
- The Subject Device "Atomica Planner" has the same technological characteristics as the predicate device, both devices are (Stand-alone) Software Applications designed to run on standard PC platforms with similar (Software & Hardware) requirements and Platforms Compatibility with (Microsoft Windows OS - PC/Laptops).
- Both medical devices are stand-alone software applications with NO contact with patients.
- Both medical devices have the similar Indication for Use (IFU), Scientific Concept, and the same Operational Principles
- Both medical devices have the same System Intended User Profile Characteristics (Persona).
- Both medical devices are intended for the same patient population, and also for the same dental medical conditions.
- Both medical devices share the following same software design specifications, process workflow, and system functionalities:
  - ✓ Same System Input & Output Data/Files types.
  - ✓ Same Image processing/visualization of the patient's imported CT imaging datasets (DICOM standards conformance).
  - ✓ Same Image Segmentation functions along with measurement tools to evaluate & detect suitable implant placements (i.e. position distance & angles measurements).
  - ✓ Same Exporting plans dataset outputs with printable final surgical report and 3D model images of patients' surgical guides.

6.3. Technological Differences: 807.100(b)(2)(ii)(C)

- By comparing the technological characteristics of the subject device "Atomica Planner" with the predicate device "3Shape Implant Studio", the only difference found is the "Dentures" feature which the predicate device has and doesn't exist in the subject device "Atomica Planner". However, this (Minor) difference or the absence of this feature does not raise any new/unknown questions about the safety, performance, or effectiveness of the "Atomica Planner" device, since this feature is an additional/extra option.
- Also, there are some UI screens' (Minor) differences in terms of the two systems' screens objects' places, shapes, or colors for some buttons & icons; that are considered cosmetic and don't affect functional similarity between the subject device and predicate device, nor raise new safety or effectiveness questions.
- All found (Minor) technologica differences do not have an impact on the safety and effectiveness of Atomica Planner system concerning the 2D/3D visualization and segmentation of imaging information, implants placement measurements, or any other preoperative treatment planning tasks/options.

7. Performance Data

The following performance data were provided in support to demonstarte similarities to the (US Legally Marketed) predicate device: "3Shape Implant Studio".

7.1. Summary of Non-Clinical Performance Testing: 807.92(b)(1)

- Non-clinical testing for the device "Atomica Planner" was conducted and supported with verification and validation software testing during product development. The testing results support that all the software specifications have met the acceptance criteria.
- Actual results of implemented (real-world) Software Functional & Non-Functional dynamic tests/verification: (Code review/Unit, module, integration, and E2E System tests) did not show any significant design differences between both devices. All V&V results ensure the "Atomica Planner" software device's effectiveness and reliability. and also support the equivalence with the performance of the predicate device's major image processing modules/features.
- "Atomica Technology" claims conformance to the following § 892.2050 (LLZ) - Recognized Consensus Standards:
  - NEMA PS 3.1 - 3.20 2021e [Digital Imaging and Communications in Medicine (DICOM)]
  - **IEC 62304:2006** (Medical Devices - Software Lifecycle processes)
  - **IEC 62366-1:2015** (Application of Usability Engineering to Medical Devices)
  - **ISO 13485:2016** (Medical Devices - Quality Management Systems)
  - **ISO 14971:2019** (Application of Risk Management to Medical Devices)
  - **IEC TR 80001-2-2:2012** (Guidance for the communication of Medical Device Security needs, and Controls)
- Interoperability:
  DICOM (Declaration of Conformity):
  The validation has been performed on patients' DICOM datasets to ensure that the "Atomica Planner" software device complies with the NEMA PS 3.2 conformance standards, the same as the predicate device does. DICOM Statements validation result has demonstrated that successful medical imaging dataset/information exchange is possible using Atomica Planner software.
- Software Verification and Validation:
  In accordance with the FDA's Guidance Document:
  "FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices) May 11, 2005 ";
  documentation is included within this submission for software of a **Moderate Level of Concern**.
  Non-clinical Testing was conducted during product development. Evidence provided within this submission demonstrates conformance with special controls for medical devices containing software.
- Cybersecurity considerations related to "Atomica Planner" are included within this submission. "Atomica Technology" conforms to cybersecurity requirements by implementing a means to prevent unauthorized access, modification, misuse, denial of use or unauthorized use of information stored, accessed or transferred from a medical device to an external recipient. The data communication is secured using the SSL and TLS protocols. The core library (written in C++ programming language) implements the basic cryptographic functions and provides various utility/security functions:
  - ✓ Provides secure communication over the internet through encrypting & decrypting data
  - ✓ It is used for sending the application's log file in an error report to the support team when the application crashes.
  - ✓ Prevents intruders from listening to server communication.
  - ✓ Use asymmetric encryption for connection establishment then, it allows symmetric encryption for the client and the server for faster connection.
- Risk Analysis, in compliance with ISO 14971, for "Atomica Planner" was completed and risk control implemented to mitigate identified hazards. Testing results support that all the software specifications have met the acceptance criteria.

- Software Usability Validation (Human Factors) – IEC 62366-1:2015:
  The Usability Validation Evaluations (Formative & Summative) activities & results have been implemented, and results have been defined and reported in a separate (Atomica Planner System Usability) document. The Usability Testing practices have been done in accordance with **IEC 62366-1:2015** and have been defined and completed by real end-users (Dental professionals. The scope was to validate that end users can use the software effectively and safely. Implementing system Design Demos for usability validation/evaluations by real endusers (Dental professionals) during the "Atomica Planner" SDLC.The system UX Design standards have been validated: (e.g. GUI screens element density, layout and flow, colors, metaphors, keyboard shortcuts...etc.). Localization/Internationalization requirements have been validated: (e.g. languages, spellings, capitalization… etc.) to achieve a high-quality level of our business objectives and ensure compliance with medical safety Human Factors standards.
- Based on conclusions drawn from the non-clinical verification tests on "Atomica Planner" system's image processing performance & accuracy, in terms of (image rendering, image contrast, anatomical coverage, anatomical structures, density, ROI, angle, and implant position measures) and according to validating DICOM standards conformance; the "Atomica Planner" software medical device is as effective as and performs as the legally marketed predicate device, and with no significant technical differences.

7.2. Clinical Testing: 807.92(b)(2)

No clinical studies were carried outfor "Atomica Planner". All performance testing was conducted in a non-clinical fashion as part of the verification and validation activities for the medical device.

8. Conclusion

- "Atomica Planner" was developed under the Quality System Regulation using Design Controls 21 CFR 820.30. This included establishing and maintaining procedures to ensure design requirements are met. All elements of the process have been documented, including the design and development plan, design input, design output, design review, design verification, design validation, design transfer, design changes, and design history file.
- Performance tests were conducted for "Atomica Planner" software device functionalities during the software development lifecycle. These tests have been performed to assess the effectiveness of the subject device. The results of all tests were acceptable in support to determine similarities to the (US legally marketed) predicate device. Also, the provided evidence demonstrates conformance with special controls for software medical devices.
- Atomica Quality Management System is applying early Risk management implementation throughout the software development lifecycle to control potential safety hazardous situations using comprehensive assessment methods for the frequency, severity, and impact of all found software defects/issues. Besides the Cybersecurity strategy for identifying & monitoring IT threats to safeguard/mitigate related vulnerabilities (e.g prevent unauthorized access, modification, misuse, denial of use, or unauthorized use of information stored, accessed, or transferred from the medical device to any external recipient… etc.). Device labeling contains technical instructions for use and any necessary cautions and warnings to provide for patient safety and effective use of this device.
- "Atomica Planner" software does not come in contact with patients, and will not expose patients to an unreasonable or significant risk of illness or injury, it's not self-driven. The treatment plan should be created only by a well-trained dental professional in order to guide him through the implant surgery and provide information about the patient such as (bone density, visualization, and measurements). This decreases the chance of causing any direct harm to the patient, as the software serves as an advisory to the dentist and not a replacement for him; so the dentist still has the authority and time to revise the system outputs' datasets.
- The comparison of intended use, technological characteristics, performance specifications, device hazards as well as verification and validation results demonstrate that the "Atomica Planner" software device is safe, effective, and as performs as the (US Legally Marketed) predicate device.
- In summary, "Atomica Technology" is of the opinion that "Atomica Planner" software (Version 3.0.0) does not introduce any new significant potential technical effectiveness concerns or human safety risks, and is similar to the predicate device.

9. FDA Guidance

- "Content of Premarket Submissions for Software Contained in Medical Devices"
- "General Principles of Software Validation; Final Guidance for Industry and FDA Staff"
- "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices"