November 1, 2019

Medtronic Navigation, Inc.
Jason Woehrle
Senior Regulatory Affairs Specialist
826 Coal Creek Circle
Louisville, Colorado 80027

Re: K191597
Trade/Device Name: Stealth Autoguide System, Midas Rex Legend Depth Stop System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW, HBC, HBB, HBE
Dated: September 27, 2019
Received: October 2, 2019

Dear Jason Woehrle:

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,

Matthew Krueger
Assistant 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191597

Device Name
Stealth Autoguide™ System

Indications for Use *(Describe)*
The Stealth Autoguide™ System is a positioning and guidance system intended for the spatial positioning and orientation of instrument holders or tool guides to be used by neurosurgeons to guide standard neurosurgical instruments, based on a pre-operative plan and feedback from an image-guided navigation system with three-dimensional imaging software.

The Stealth Autoguide™ System is a remotely-operated positioning and guidance system, indicated for any neurological condition in which the use of stereotactic surgery may be appropriate (for example, stereotactic biopsy, stereotactic EEG, laser tissue ablation, etc.).

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191597

Device Name
Midas Rex™ Legend™ Depth Stop System

Indications for Use *(Describe)*
The Midas Rex™ Legend™ depth stop attachment and tools are indicated for the incision, cutting, removing, and drilling of soft and hard tissue during cranial surgical procedures with the intent to create a hole through the cranium to allow surgeons access to desired surgical locations and/or to facilitate insertion, placement of other surgical devices during such procedures.

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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510(k) Summary
June 14, 2019

I. **Company:** Medtronic Navigation, Inc.
826 Coal Creek Circle
Louisville, Colorado 80027 USA
Telephone Number: 720-890-3200

Medtronic Powered Surgical Systems
4620 N Beach Street
Ft Worth, TX 76137 USA

Contact: Jason Woehrle (Primary)
Senior Regulatory Affairs Specialist
Telephone Number: 949-399-1509
Fax Number: 720-890-3500

K. Elizabeth Waite (Alternate)
Principal Regulatory Affairs Specialist
Telephone: (720)-890-2182
Fax: 720-890-3500

II. **Proprietary Trade Name**:
Stealth Autoguide™ System
Midas Rex™ Legend™ Depth Stop System

III. Common Name:
Stealth Autoguide™ System: Stereotaxic Instrument
Midas Rex™ Legend™ Depth Stop System: Motor, Drill, Electric, Motor, Drill, Pneumatic, Powered simple cranial drills, burrs, trephines, and their accessories

IV. Classification Name:
Stealth Autoguide™ System: Stereotaxic Instrument (21 CFR 882.4560)
Midas Rex™ Legend™ Depth Stop System: Electric cranial drill motor (21 CFR 882.4360) Pneumatic cranial drill motor (21 CFR 882.4370) Powered simple cranial drills, burrs, trephines, and their accessories (21 CFR 882.4310)

V. Classification:
Stealth Autoguide™ System: Class II
Midas Rex™ Legend™ Depth Stop System: Class II

VI. Product Code:
Stealth Autoguide™ System: HAW
Midas Rex™ Legend™ Depth Stop System: HBC, HBB, HBE

VII. Product Description:

Stealth Autoguide™ System: The Stealth Autoguide System is a robotic positioning and guidance system intended to interpret navigation tracker coordinates and surgical plan coordinates from the StealthStation to robotically position and orient instrument holders or tool guides to be used by neurosurgeons to guide standard neurosurgical instruments to pre-defined plans.

Midas Rex™ Legend™ Depth Stop System: The Midas Rex™ Legend™ Depth Stop System consists of a Depth Stop Attachment and specific surgical dissecting tools that will be used in conjunction with the Stealth Autoguide System to create cranial access holes for neurosurgical procedures.

VIII. Indications for Use:

Stealth Autoguide™ System: The Stealth Autoguide System is a remotely-operated positioning and guidance system, indicated for any neurological condition in which the use of stereotactic surgery may be appropriate (e.g., stereotactic biopsy, stereotactic EEG, laser tissue ablation, etc.).

Midas Rex™ Legend™ Depth Stop System: The Midas Rex™ Legend™ depth stop attachment and tools are indicated for the incision, cutting, removing, and drilling of soft and hard tissue during cranial surgical procedures with the intent to create a hole through the cranium to allow surgeons access to desired surgical locations and/or to facilitate insertion, placement of other surgical devices during such procedures.

IX. Identification of Legally Marketed Devices (Predicate Devices):

Stealth Autoguide™ System:

Predicate: K151359 – ROSA Brain, manufactured by MEDTECH S.A
Reference Devices: K131433 – iSYS1, manufactured by ISYS
Reference Devices: K162309 – StealthStation S8 Cranial, manufactured by Medtronic Navigation, Inc.
Reference Devices: K162604 – Cranial Reducing Tubes, manufactured by Medtronic Navigation, Inc.

Midas Rex™ Legend™ Depth Stop System:

Predicate: K170312, K163182 – Midas Rex Legend Electric and Pneumatic Drill Systems, manufactured by Medtronic Powered Surgical Systems.

X. Summary of the Technological Characteristics:

Stealth Autoguide™ System

Item	Subject Device	Predicate Devices
General Description	Computer controlled electromechanical multi-jointed arm for use as a stereotactic instrument	**Predicate: ROSA Brain (K151359)** Computer controlled electromechanical multi-jointed arm for use as a stereotactic instrument
Product Code	HAW	**Predicate: ROSA Brain (K151359)** HAW
Intended Use/ Indications for Use	The Stealth Autoguide™ System is a positioning and guidance system intended for the spatial positioning and orientation of instrument holders or tool guides to be used by neurosurgeons to guide standard neurosurgical instruments, based on a pre-operative plan and feedback from an image-guided navigation system with three-dimensional imaging software. The Stealth Autoguide™ System is a remotely-operated positioning and guidance system, indicated for any neurological condition in which the use of stereotactic surgery may be appropriate (for example, stereotactic biopsy, stereotactic EEG, laser tissue ablation, etc.).	**Predicate: ROSA Brain (K151359)** Intended for the spatial positioning and orientation of instrument holders or tool guides to be used by neurosurgeons to guide standard neurosurgical instruments (biopsy needle, stimulation or recording electrode, endoscope). The device is indicated for any neurosurgical procedure in which the use of stereotactic surgery may be appropriate. **Reference Device: iSYS 1 (K131433)** The iSYS 1 device is intended to assist the surgeon in the positioning of a needle or electrode where both computed tomography (CT) and fluoroscopic imaging can

Item	Subject Device	Predicate Devices
		be used for target trajectory planning and intraoperative tracking. The needle or electrode is then manually advanced by the surgeon. Trajectory planning is made with software that is not part of the iSYS device.
Operating Principle	Preoperative images (StealthStation) Surgical planning (StealthStation) Patient registration Guidance of instruments	**Reference Device: iSYS 1 (K131433)** Preoperative images (third party) Surgical planning (third party) Patient registration Guidance of instruments
Localization Means	Optical markers on tool holder	**Reference Device: Stealth S8 Cranial (K162309)** Optical markers on tool holder
Image-Guided	Yes (on StealthStation)	**Reference Device: iSYS 1 (K131433)** Yes
Planning Software	Compatible with: S8 Cranial v1.1 Synergy Cranial v.3.1	**Reference Device: Stealth S8 Cranial (K162309)** S8 Cranial v1.2
System Accuracy Requirement	Under representative worst-case configuration, the StealthStation® System with Cranial Software used with Stealth Autoguide™ System, has demonstrated performance in 3D positional accuracy with a mean error ≤ 2.0 mm and in trajectory angle accuracy with a mean error ≤ 2.0 degrees.	**Reference Device: Stealth S8 Cranial (K162309)** Under representative worst-case configuration, the StealthStation® System S8 with StealthStation™ Cranial v1.0.0 Software, has demonstrated performance in 3D positional accuracy with a mean error ≤ 2.0 mm and in trajectory angle accuracy with a mean error ≤ 2.0 degrees.
Instrumentation	Navigated Trajectory Guide Tool Holders (Drill Guides, Reducing Tubes) Height Guides Tapping Tube	**Reference Device: Cranial Reducing Tubes (K162604)** Navigated Trajectory Guide Tool Holders (Drill Guides, Cranial reducing Tubes

Item	Subject Device	Predicate Devices
		Height Guides Tapping Tube
Instrument Fixation	Special tool holders for different applications mounted to the Stealth Autoguide	**Reference Device: iSYS 1 (K131433)** Special tool holders for different applications mounted to the device
Guide Position Adjustment	Robotic movement	**Predicate: ROSA Brain (K151359)** Automatic (Robotized)
Accessories	Sterile Drapes Head Frame Adapter Cable Sets	**Reference Device: iSYS 1 (K131433)** Sterile Drapes Table Adapters Cable Sets
Real-Time Instrument Position	Yes (on StealthStation)	**Reference Device: iSYS 1 (K131433)** Yes
Patient Registration	Optical Registration Device (via StealthStation)	**Reference Device: Stealth S8 Cranial (K162309)** Optical Registration Device (via StealthStation)
Surgeon Performs Final Instrument Delivery through Instrument Guide	Yes	**Reference Device: iSYS 1 (K131433)** Yes

Midas Rex™ Legend™ Depth Stop System:

Feature/ Attribute	Subject Devices Midas Rex™ Legend™ Depth Stop	Electric Drill Expanded Indications (K170312)	Pneumatic Drill Expanded Indications (K163182)
Product Code	HBC, HBB, HBE	HBE, HBC, HRX, HWE, EQJ, ERL, KFK	KFK, HBB, ERL, EQJ, HSZ, GET, KFK, HBE, DWH
Intended Use	Incision, cutting, removing, and drilling of soft and hard tissue	Incision/ cutting, removal, drilling, and sawing of soft and hard tissue, bone, and biomaterials.	Incision/ cutting, removal, drilling, and sawing of soft and hard tissue, bone, and biomaterials.
Indications for use	The Midas Rex Legend Depth Stop attachment and tools are indicated for the incision, cutting, removing, and drilling of soft and hard tissue during cranial surgical procedures with the intent to create a hole through the cranium to allow surgeons access to desired surgical locations and/or to	The Medtronic Electric Drill System is indicated for the incision/cutting, removal, drilling, and sawing of soft and hard tissue, bone, and biomaterials in Neurosurgical (Cranial, Craniofacial) including craniotomy; as well as Ear, Nose and Throat (ENT), Orthopedic, Arthroscopic, Spinal, and General Surgical Procedures including Maxillofacial, Craniofacial and Sternotomy Surgeries. Additionally, the Electric Drill System is indicated for the incision / cutting, removal, drilling, and sawing of soft and hard tissue, bone, and biomaterials during open and minimally invasive spine procedures, which may incorporate application	The Medtronic Pneumatic Drill System is indicated for the incision/cutting, removal, drilling, and sawing of soft and hard tissue, bone, and biomaterials in Neurosurgical (Cranial, Craniofacial) including craniotomy; as well as Ear, Nose and Throat (ENT), Orthopedic, Arthroscopic, Spinal, and General Surgical Procedures including Maxillofacial, Craniofacial and Sternotomy Surgeries. Additionally, the Pneumatic Drill System is indicated for the incision / cutting, removal, drilling, and sawing of soft and hard tissue, bone, and biomaterials during open and minimally invasive spine procedures, which may incorporate application of various surgical techniques during the following lumbar spinal procedures: • Lumbar Microdiscectomy • Lumbar Stenosis

Feature/ Attribute	Subject Devices Midas Rex™ Legend™ Depth Stop	Electric Drill Expanded Indications (K170312)	Pneumatic Drill Expanded Indications (K163182)
	facilitate insertion, placement of other surgical devices during such procedures.	of various surgical techniques during the following lumbar spinal procedures: • Lumbar Microdiscectomy • Lumbar Stenosis Decompression • Posterior Lumbar Interbody Fusion (PLIF) • Transforaminal Lumbar Interbody Fusion (TLIF)	• Posterior Lumbar Interbody Fusion (PLIF) • Transforaminal Lumbar Interbody Fusion (TLIF) • Anterior Lumbar Interbody Fusion (ALIF) • Direct Lateral Interbody Fusion (DLIF)
General System Components	Attachment, Surgical Dissecting Tool	Electric Handpiece, Attachments, Surgical Dissecting Tools, System Accessories	Pneumatic Handpiece, Attachments, Surgical Dissecting Tools, System Accessories
Patient Contacting Components	Attachment and Surgical Dissecting Tools	Attachments and Surgical Dissecting Tools	Attachments and Surgical Dissecting Tools
Materials of Patient Contacting Components	Attachment - Stainless Steel, Phenolic, Chevron SRI Grease 2 Surgical Dissecting Tools –Tool Steel	Attachments - Stainless Steel, Aluminum, Ceramic, Phenolic, Epoxy, Chrome Coated Brass, Torlon 4301 Dissecting Tools: Stainless Steel, Tool Steel, Alloy Steel, Carbide, TDC Coating, Diamond Coating in	Attachments - Stainless Steel, Aluminum, Ceramic, Phenolic, Epoxy, Chrome Coated Brass, Polymeric Dissecting Tools: Stainless Steel, Tool Steel, Alloy Steel, Carbide, TDC Coating, Diamond Coating in Nickel Substrate, Titanium Nitride

Feature/ Attribute	Subject Devices Midas Rex™ Legend™ Depth Stop	Electric Drill Expanded Indications (K170312)	Pneumatic Drill Expanded Indications (K163182)
		Nickel Substrate, Titanium Nitride	
Surgical Dissecting Tools – Tip Style	Twist Drill	Round/Acorn, Match Head, Ball, Cylinder, Oval, Tapered/Side Cutting, Metal Cutting, Twist Drill, Hole Maker/Saw,	Round/Acorn, Match Head, Ball, Cylinder, Oval, Tapered/Side Cutting, Metal Cutting, Twist Drill, Hole Maker/Saw, Reverse Tapered
Surgical Dissecting Tool - Overall Length	Surgical Dissecting Tool: 6.7-8.7cm	Surgical Dissecting Tool: 3-42cm	Surgical Dissecting Tool: 3-42cm
Surgical Dissecting Tool - Head Diameter	Surgical Dissecting Tool: 2.5 – 7.5mm	Surgical Dissecting Tool: 0.5-25mm	Surgical Dissecting Tool: 0.5-25mm
Attachment Configuration	Depth Stop	Straight, Angled, Footed, Contra Angled, Right Angled, Metal Cutting, Depth limiting Drill Guides, Perforator, Jacob Chuck Attachments, Wire/Pin Collet Attachments	Straight, Angled, Footed, Contra Angled, Right Angled, Metal Cutting, Depth limiting Drill Guides, Perforator, Jacob Chuck Attachments, Wire/Pin Collet Attachments
Attachment Length	ASDS01 13.7cm - 14.8cm in 1mm increments	2-40cm	2-40cm
Drill System Operating Principle	Electric powered by IPC and Pneumatic powered by Pneumatic Pressure	Electric powered by IPC	Pneumatic powered by Pneumatic Pressure

Feature/ Attribute	Subject Devices Midas Rex™ Legend™ Depth Stop	Electric Drill Expanded Indications (K170312)	Pneumatic Drill Expanded Indications (K163182)
Packaging – Single Use Dissecting Tools	The Surgical Dissecting Tools are individually packaged in a Propionate cellulosic plastic capped tube and sealed within a 4 mil PET-Nylon-HDPE Co-Ex (Peel Seal)/4 mil PET-Nylon-EVA Pouch.	The Surgical Dissecting Tools are individually packaged in a Propionate cellulosic plastic capped tube and sealed within a 4 mil PET-Nylon-HDPE Co-Ex (Peel Seal)/4 mil PET-Nylon-EVA Pouch.	The Surgical Dissecting Tools are individually packaged in a Propionate cellulosic plastic capped tube and sealed within a 4 mil PET-Nylon-HDPE Co-Ex (Peel Seal)/4 mil PET-Nylon-EVA Pouch.
Sterilization	Surgical Dissecting Tools are supplied Gamma Sterilized Non-sterile, Attachments	Surgical Dissecting Tools are supplied Gamma Sterilized; - Electric Handpieces, and Attachments are supplied Non-Sterile and require cleaning and sterilization prior to each surgical use; - Electric Foot Control Unit, and System Accessories are supplied Non-Sterile.	Surgical Dissecting Tools are supplied Gamma Sterilized; - Pneumatic Handpieces, and Attachments are supplied Non-Sterile and require cleaning and sterilization prior to each surgical use; - Pneumatic Foot Control Unit, and System Accessories are supplied Non-Sterile.
Shelf Life	5 years for Surgical Dissecting Tools	5 years for Surgical Dissecting Tools	5 years for Surgical Dissecting Tool

XI. Discussion of the Performance Testing:

Testing conducted demonstrates the product will perform as intended according to the outlined design requirements. The following testing was conducted on the Stealth Autoguide™ System and Midas Rex™ Legend™ Depth Stop System to establish substantial equivalence of the system and verify that the device will perform as intended meeting all the design inputs:

- AAMI/ANSI ES 60601-1:2012 - Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2:2014 - Medical Electrical Equipment – Part 1-2: General requirements for safety; Electromagnetic Compatibility – Requirements and Tests
- Software Verification and Validation testing verifying the operating system software requirements are met and software performs as intended
- Hardware Verification testing ensuring the hardware requirements identified for the system are met and hardware performs as intended
- Usability Testing was conducted in accordance to IEC 62366 demonstrating that the usability and human factors requirements were adequately met.

The following table summarizes the testing conducted on the Stealth Autoguide™ System when used with the StealthStation™ System and Stealth Cranial Software

Description
Under representative worst-case configuration, the Stealth Autoguide™ System when used with the StealthStation™ System utilizing Stealth Cranial Software, has demonstrated performance in 3D positional accuracy with a mean error ≤ 2.0 mm and in trajectory angle accuracy with a mean error ≤ 2.0 degrees. The performance was determined using overall end-to-end worst-case system level accuracy testing which incorporated clinically relevant anatomical phantoms. To exercise the performance and impact of the Stealth Autoguide™ System utilizing Stealth Cranial software, four distinct end-to-end worst-case configuration pathways were identified. The following table summarizes the performance of the Stealth Autoguide™ System when used with the StealthStation™ System (S7 and S8) utilizing Stealth Cranial Software with Biopsy and sEEG bolts/Visualase.

Performance Validation	Positional Error (mm)			Trajectory Angle Error (degrees)		
	Mean	Standard Deviation	99% CI* Upper	Mean	Standard Deviation	99% CI* Upper
Biopsy Needle Accuracy Validation-StealthStation S7	0.92	0.47	3.03	1.22	0.51	2.41
Biopsy Needle Accuracy Validation-StealthStation	0.97	0.26	1.70	0.59	0.23	1.11

S8						
sEEG bolts/Visualase Accuracy Validation-StealthStation S7	1.50	0.68	3.08	1.04	0.76	2.81
sEEG bolts /Visualase Accuracy Validation-StealthStation S8	1.48	0.48	2.60	0.42	0.17	0.82
*CI (confidence interval)						

The following tables summarize the biocompatibility studies Medtronic sponsored on the Midas Rex Legend Depth Stop System and Stealth Autoguide Surgical Instruments.

Cytotoxicity, sensitization, intracutaneous reactivity and material-mediated pyrogenicity studies were conducted on the extractables and leachables (E&L) of representative Midas Rex Legend Depth Stop System Attachment and Tools (ASDS01 and DS1TD75), as well as Stealth Autoguide Surgical Instruments (28324). A toxicological risk assessment was also performed. The Midas Rex Legend Depth Stop Attachment (ASDS01) is the only attachment for the Midas Rex Legend Depth Stop System and thus, does not represent any other devices. The 7.5mm Depth Stop Twist Drill Tool (DS1TD75) is representative of all Midas Rex Legend Depth Stop Tools. The Visualase Drill Guide (28324) is representative of all Stealth Autoguide Surgical Instruments.

Test	Results	Conclusions
Chemical characterization – Extractables and Leachables (polar and nonpolar) Toxicological Risk Assessment	All MOS > 1.0, All HI < 1.0	Non-toxic
Cytotoxicity – ISO MEM Elution	% Rounding – 0; % w/o Intracytoplasmic Granules – 0; % Lysis – 0; Grade – 0 Reactivity – None.	Non-cytotoxic
Sensitization – 2 solvents	Dermal Reaction Scores 24-hr control, test; 48-hr control, test) SC Extract: 0, 0; SO Extract: 0, 0	Non-sensitizing
Intracutaneous Reactivity/ Irritation – 2 solvents	Overall Erythema & Edema Mean Difference (Test - Control) SC Extract = 0; SO Extract = 0	Non-irritating

Material-mediated Pyrogenicity	DS1TD75 Individual Rise (°C): 0.3, 0.0, 0.0 Total Rise (°C): 0.3 ASDS01 Individual Rise (°C): 0.2, 0.3, 0.1 Total Rise (°C): 0.6 28324 Individual Rise (°C): 0.1, 0.2, 0.1 Total Rise (°C): 0.4	Non-pyrogenic

Material-mediated pyrogenicity testing and an additional hemolysis characterization test were sponsored on the Stealth Autoguide Burr Hole Reducing Tube (28334). The Stealth Autoguide Burr Hole Reducing Tube (28334) is representative for all Stealth Autoguide Reducing Tubes.

Test	Results	Conclusions
Material-mediated Pyrogenicity	Temp., °C, Rise (1, 1.5, 2, 2.5, 3 hr) 0, 0.1, 0, 0, 0.2	Non-pyrogenic
Hemolysis (extract)	Diluted blood Abs: 0.380 – 0.397; Direct Contact Hemolytic Index: 1.2%; Extract – Hemolytic Index: 0.2%	Non-hemolytic

XII. Conclusions:

The Stealth Autoguide™ System, Instrumentation and Midas Rex™ Legend™ Depth Stop System have been shown through comparison and testing to be substantially equivalent to the identified predicate devices.