HydroCision, Inc.
% Yashesh Rawal
Regulatory Affairs Specialist II
MAE Consulting Group, LLC
119 North Road
Deerfield, New Hampshire 03037

April 16, 2020

Re: K200729
Trade/Device Name: HydroCision SpineJet System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: March 15, 2020
Received: March 20, 2020

Dear Yashesh Rawal:

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,

Jesse Muir, Ph.D.
Acting Assistant Director
DHT6C: Division of Restorative, Repair,
and Trauma 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200729

Device Name
HydroCision SpineJet System

Indications for Use *(Describe)*
The HydroCision SpineJet System is indicated for surgical procedures where the cutting and removal of soft tissue and the ablation and removal of hard tissue or bone is required. Specific functions include cutting, ablation and shaping of soft tissue, and decorticating and smoothing of bone, cartilage and other bone related tissue in open and minimally invasive in spinal surgeries.

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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Section 5- 510(k) Summary

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the HydroCision SpineJet System.

5.1. Applicant:

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5.2. Sponsor Contact Person:

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5.3. Regulatory Correspondent/ 510(k) Submission Contact:

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5.4. Date Prepared: March 13, 2020

5.5. Device Information:

Proprietary Name: HydroCision SpineJet System

Device:	HydroCision SpineJet System
Panel:	Orthopedic
Regulatory Number:	21 CFR 880.1100
Regulation Name:	Arthroscope
Product Code:	HRX
Device Class:	Class II

5.6. Predicate Device:

HydroCision ArthroJet with Cautery, TurboBurr and Curette (K041233). HydroCision ArthroJet System has been rebranded to HydroCision SpineJet System.

The purpose of this Special 510(k) submission is to implement design changes to the predicate ArthroJet System (K041233) to create a product line extensions with additional working length to encompass different configurations of SpineJet handpiece models and remove obsolete components for Cautery, TurboBurr and Curette from the predicate device. These modifications to the 510(k) cleared ArthroJet System do not change the indications for use of the device, nor do they change the fundamental scientific technology of the device.

5.7. Device Description:

The HydroCision SpineJet System comprises of (i) sterile disposable tubing assembly- SpineJet device and (ii) reusable console unit- HydroCision Console. The components of SpineJet device consists of a pump cartridge, handpiece and tubing assembly (also known as disposable hose). The SpineJet device is provided sterile, via ethylene oxide sterilization. The reusable HydroCision Console are packaged and sold separately. The SpineJet device is designed to be used in combination with the HydroCision console as a SpineJet system. The SpineJet system is connected with a foot pedal, a sterile bag of saline, and a waste container prior to operation.

The SpineJet device pump cartridge plugs into the front of the HydroCision Console. This connection provides power to the SpineJet device and pressurizes the saline to deliver to the tip of the SpineJet handpiece through high pressure saline tube. The SpineJet handpiece consists of a plastic handle and a two-lumen needle: high pressure tube lumen and evacuation tube lumen, which are welded together in the handle. As the high-pressure saline passes from one lumen nozzle to another lumen nozzle, the targeted tissues are cut, debrided and removed into the evacuation tube lumen, passing into the waste container. The SpineJet tubing assembly (also known as disposable hose) consists of three tubes: (i) Clear saline supply tube (fluid supply hose) - which delivers saline from saline bag to pump cartridge (ii) High pressure saline tube- which delivers pressurized saline from the pump cartridge to the tip of SpineJet handpiece and (iii) Evacuation tube (waste hose) - which removes debrided tissue, along with saline from tip of the handpiece and delivers it to waste container, which is provided by the facility.

The Hydrocision Console (K190804) is an electrically powered device. It provides the power to pressurize sterile saline fluid, which is delivered to the distal tip of the SpineJet handpiece. The HydroCision console includes the software functionality to provide touch-screen LCD display and graphical user interface.

To perform an open or minimally invasive spinal procedure, the SpineJet handpiece needle is inserted into the spine through cannula access set and guided toward the targeted diseased tissue under fluoroscopic guidance. Once the SpineJet handpiece needle is in position, the surgeon activates the high-pressure saline of SpineJet device using the Hydrocision console and foot pedal. Using fluoroscopic guidance, the surgeon uses the SpineJet handpiece to cut and remove the targeted diseased tissue. When the procedure is complete, the handpiece is withdrawn, and the incision is closed using steri-strips for a closed, minimally invasive procedure.

The SpineJet device is provided sterile, via ethylene oxide sterilization.

5.8. Indication for Use:

The HydroCision SpineJet System is indicated for surgical procedures where the cutting and removal of soft tissue and the ablation and removal of hard tissue or bone is required. Specific functions include cutting, ablation and shaping of soft tissue, and decorticating and smoothing of bone, cartilage and other bone related tissue in open and minimally invasive spinal surgeries.

5.9. Comparison of Technological Characteristics:

The HydroCision SpineJet System is substantially equivalent in intended use, design, performance and principles of operation to the predicate device- HydroCision ArthroJet with Cautery, TurboBurr and Curette (K041233). Both systems include same principle components- (i) SpineJet device consisting of a pump cartridge, handpiece and tubing assembly (disposable hose) and (ii) HydroCision console. The handpiece component of both devices consists of a plastic handle and a two-lumen needle welded in the handle. Both devices are designed to be connected with the HydroCision console, foot pedal, a sterile bag of saline (which is supplied by the facility), and a waste container (supplied by the facility) prior to operation. The differences in the design of the HydroCision SpineJet device and the predicate device are minor and raise no new issues of safety or efficacy. The HydroCision SpineJet device and the predicate device consist of the same technology and are sterilized with same acceptable method. Both the devices are made up of same biocompatible materials.

Below is a comparison table that provides a top-level overview of the substantial equivalent comparison between proposed and predicate devices.

Comparative Characteristics	**Proposed Device: HydroCision SpineJet System**	**Predicate Device: HydroCision ArthroJet with Cautery, TurboBurr and Curette**
510(k) Number	N/A	K041233
Indication for Use	The HydroCision SpineJet System is indicated for surgical procedures where the cutting and removal of soft tissue and the ablation and removal of hard tissue or bone is required. Specific functions include cutting, ablation and shaping of soft tissue, and decorticating and smoothing of bone, cartilage and other bone related tissue in open and minimally invasive spinal surgeries.	The HydroCision ArthroJet System with Cautery, TurboBurr, and Curette is indicated for orthopedic surgical procedures where the cutting and removal of soft tissue and the ablation and removal of hard tissue or bone is required with control of bleeding during those procedures as needed. Specific functions include cutting, ablation and shaping of the soft tissue, and drilling, reaming, decorticating and smoothing of bone, cartilage and other bone related tissue in a variety of surgical procedures including open and minimally invasive spinal surgeries and small and large joint arthroscopic procedures.
Principle of Operation	The SpineJet device uses a high-pressure saline to act as a cutting medium to debride and remove targeted tissue material in the intended procedures. As the high pressure saline flows from the one needle lumen nozzle to another at the distal tip of the SpineJet device, a Venturi effect creates localized suction pulling nearby target tissue into the path of the high pressure saline stream where it is cut, debrided and then passes into the evacuation tube to be removed.	The ArthroJet device uses a high-pressure saline to act as a cutting medium to debride and remove targeted tissue material in the intended procedures. As the high pressure saline flows from the one needle lumen nozzle to another at the distal tip of the ArthroJet device, a Venturi effect creates localized suction pulling nearby target tissue into the path of the high pressure saline stream where it is cut, debrided and then passes into the evacuation tube to be removed.
Single Use	Yes	Yes
Principle System Components	Handpiece, Pump Cartridge and Tubing Assembly	Handpiece, Pump Cartridge and Tubing Assembly

Comparative Characteristics	**Proposed Device: HydroCision SpineJet System**	**Predicate Device: HydroCision ArthroJet with Cautery, TurboBurr and Curette**
(Sterile, Disposable, Single Use)		
Principle System Components/ Other devices for interfacing (Reusable)	HydroCision Console Unit, Foot Pedal	HydroCision Console Unit, Foot Pedal
Accessories/ Convenience Kit	No	No
Sterilization	Supplied Sterile, EtO Sterilization	Supplied Sterile, EtO Sterilization
Materials		
Handpiece Handle	ABS	ABS
Handpiece Needle	Stainless Steel	Stainless Steel
Pump Cartridge	Stainless Steel	Stainless Steel
High Pressure Tubing Assembly	Polyamide	Polyamide
Evacuation Tubing Assembly	Polyurethane	Polyurethane
Medical Adhesive	Loctite #4011	Loctite #4011
Biocompatibility of Materials	Meets ISO 10993-1 requirements	Meets ISO 10993-1 requirements
Technical Features/Design		
Tubing Assembly Dimension (Disposable Hose)	High Pressure Hose - 0.143”OD, 0.050” ID Evacuation Tube Hose - 0.125”OD, 0.059” ID	High Pressure Hose - 0.143”OD, 0.050” ID Evacuation Tube Hose - 0.125”OD, 0.059” ID
Pump Cartridge Dimension	Handle Cartridge – Length – 2.00” Piston Body- Length- 1.860 Suction Connector- Length- 1.6”	Identical. Handle Cartridge – Length – 2.00” Piston Body- Length- 1.860 Suction Connector- Length- 1.6”

Comparative Characteristics	Proposed Device: HydroCision SpineJet System	Predicate Device: HydroCision ArthroJet with Cautery, TurboBurr and Curette
Handpiece Dimension	Include models of additional length. The dimensional range of Modified device is within the dimensional specification cleared for the predicate device- ArthroJet system. Tubing Assembly: High Pressure Hose - 0.143"OD, 0.050" ID Evacuation Tube Hose - 0.125"OD, 0.059" ID Handle: (Identical) Device Handle Weldment Length- 4.593" Needle: High Pressure lumen/jet tube- 0.045 OD, 0.020 ID Evacuation Tube lumen- 0.072 OD, 0.063 ID Needle Angle: 10 Deg, 20 Deg, 30 Deg, 75 Deg Working Shaft Length (Needle Length) - Additional Models: 6.70", 7.61", 7.62", 7.66", 7.739", 7.76", 8.28", 8.30", 8.92", 8.96", 13.78"	Tubing Assembly: (Identical) High Pressure Hose - 0.143"OD, 0.050" ID Evacuation Tube Hose - 0.125"OD, 0.059" ID Handle: (Identical) Device Handle Weldment Length- 4.593" Needle: (Identical) High Pressure lumen/jet tube- 0.045 OD, 0.020 ID Evacuation Tube lumen- 0.072 OD, 0.063 ID Needle Angle: (Identical) 10 Deg, 20 Deg, 30 Deg, 75 Deg Working Shaft Length (Needle Length): 6.7", 13.78"

Comparative Characteristics	**Proposed Device: HydroCision SpineJet System**	**Predicate Device: HydroCision ArthroJet with Cautery, TurboBurr and Curette**
Device Needle	The SpineJet handpiece needle consists of two lumens: high pressure tube lumen and evacuation tube lumen, which are welded together. The high-pressure lumen delivers high pressure saline to the target tissue site. The evacuation lumen evacuates the saline and debrided tissue material from the target tissue site.	Identical
High Pressure Saline Flow Rate (at the pump cartridge)	230 ml/min at 15,000 psi 156 ml/min at 7,500 psi	230 ml/min at 15,000 psi 156 ml/min at 7,500 psi
HydroCision Console	Dimensions: 8.7" W x 17.5" D x 11.5" H Weight: 30lbs Power: 100-240 V ~ 6A 50/60 Hz Software driven (K190804)	Dimensions: 16" W x 13" D x 7" H Weight: 28lbs Power: 100-240 V ~ 6A 50/60 Hz Not Software Driven (K041233)
Packaging Description	Blister tray, Tyvek led seal, Tyvek pouch, unit box.	Sealed mylar/Tyvek pouch or a PETG tray with a sealed Tyvek lid.
Do the Devices Have the Same Indication for Use and Technological Characteristics and are substantially equivalent?	<u>Indications for Use Statement:</u> • The indications for use statements are nearly identical for the two devices except that the predicate device is also indicated for use drilling and reaming of bone, cartilage and other bone related tissue in a variety of surgical procedures. The predicate device includes additional components for drilling and reaming which are TurboBurr, Cautery and Curette. These components are obsoleted and removed for the HydroCision SpineJet device. The claims associated with the obsolete components were removed from the indication for use of SpineJet device. • The indications for use of the HydroCision SpineJet device is a subset of the predicate device indication for use. Both the HydroCision SpineJet device and the predicate device are single use disposable devices indicated for use surgical procedures where the cutting and removal of soft tissue and the ablation and removal of hard tissue or bone is required. Technological Characteristics • The HydroCision ArthroJet System has been re-branded to HydroCision SpineJet system with the dimensional changes to handpiece and removal of obsolete components.	

Comparative Characteristics	Proposed Device: HydroCision SpineJet System	Predicate Device: HydroCision ArthroJet with Cautery, TurboBurr and Curette
	• The SpineJet handpiece utilizes the same biocompatible materials as the predicate device. • The SpineJet System meets the adequate performance tests specification as the predicate device in terms of EMC and electrical safety test requirements, usability requirements tested to internationally recognized standards and critical functional requirements tested to internal bench test procedures which was used for testing predicate device in previous 510(k). • Device safety, functionality, and performance characteristics of the modified SpineJet System were tested to the adequate standards. This was done by testing the HydroCision SpineJet System to the standards in which the predicate device also claims conformance to demonstrate substantial equivalence. • Additional non-clinical performance bench tests used to support previously 510(k) cleared device were conducted to verify that the performance of the proposed SpineJet System is substantially equivalent to the predicate device, and that SpineJet device will perform as intended. All testing pertaining to the differences between SpineJet System and predicate device met their respective acceptance criteria as specified per the individual bench test report. • The potential hazards and use-related issues associated with the modified SpineJet System have been adequately mitigated in the SpineJet risk management file in accordance to EN ISO 14971:2012 and device user interface has been adequately demonstrated in Human Factors/Usability study. The device modification, assessed by the risk management file and validated with testing deemed necessary, does not introduce any new concerns regarding the safety and effectiveness of the subject device. Please see summary of non-clinical testing for the SpineJet device in the section 5.10 below. • The test results support the conclusion that the differences in the technological characteristics in terms of design modification is not critical and does not affect the safety and effectiveness of the device when used as labeled in accordance with 21 CFR 807.92(a)(5). Although there are slight differences in the design features of the proposed device and the predicate device, these differences were found to be insignificant overall and the principle of operation remains the same. The HydroCision SpineJet System is considered substantially equivalent to the predicate device in indication for use and technological characteristics (design and materials) based on the above evaluation.	

5.10. Summary of Testing

To ensure that the modified device design and construction are suitable for the intended use and is substantially equivalent, the HydroCision SpineJet System has been evaluated in the following tests:

- Performance Bench testing used to support previously 510(k) cleared device has been conducted to verify that the modified SpineJet device safety, functionality, and performance characteristics is substantially equivalent to the predicate device, and the SpineJet device will perform as intended.
- A Human Factors / Usability Study was conducted, and the HydroCision SpineJet System with the HydroCision Console was found to be in conformance with the IEC 62366-1:2015 Medical devices – Application of usability engineering to medical devices
- Additionally, the electromagnetic compatibility and electrical safety of the modified SpineJet device and HydroCision Console were tested and found to comply with applicable parts of the following international standards:
    - IEC 60601-1
    - IEC 60601-1-2
- Clinical evidence was not necessary to show substantial equivalence
- A risk analysis according to ISO standard "14971 Medical Devices – Application of risk management to medical devices" was carried out specifically for the changes made between the ArthroJet system and the modified HydroCision SpineJet system. Possible hazards and consequences were systematically identified and evaluated by using the "Failure Mode and Effect Analysis" technique.

5.11. Conclusion:

The modified HydroCision SpineJet system met all predetermined acceptance criteria as specified by the applicable standards, FDA guidance documents and internal test protocols. No safety and efficacy issues were raised during the testing program. Therefore, the HydroCision SpineJet System is considered substantially equivalent to the predicate device.

The safety and effectiveness of the HydroCision SpineJet system are adequately supported by the Non-Clinical performance data, substantial equivalence information, and comparison of design characteristics provided within this premarket notification.