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510(k) Summary of Safety and Effectiveness Information for the Davol Arthroscopy Pulsed Irrigator Systems

The 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

1) **Submitter Information:**

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2) **Device Name:**

Trade Name: Arthroscopy Pulsed Irrigation System
Common/Usual Name: Pulsed Irrigator
Classification Name: Jet Lavage, General Hospital Use Devices & Arthroscopes and Accessories, Orthopedic Devices

3) **Predicate Device:**

- Davol Simpulse Plus Suction Irrigator (K830386)
- Davol Simpulse SOLO Suction Irrigator (K942886)
- Arthroscopy Outflow Cannula (K894990)
- Femoral Canal Irrigation Brush Tip (K830386 & K942886)
- Microsurgical Rasp

The Pneumatic Arthroscopy Pulsed Irrigator (API) System and the Battery Arthroscopy Pulsed Irrigator (API) System proposed in this submission are substantially equivalent to Davol's currently marketed Simpulse Plus Suction Irrigator (K830386) and Simpulse SOLO Suction Irrigator (K942886). All of these devices are designed to provide pulsatile irrigation for the cleansing of surgical sites and also allow for connection to a suction source for removal of fluids or debris from the surgical site. The Arthroscopy Pulsed Irrigator (API) Irrigation/Brush Tip is also substantially equivalent to the Davol Femoral Canal Irrigation Brush Tip (K942886 and K830386) and the Acufex Microsurgical Rasp. The API Irrigation/Brush Tip, the Femoral Canal Irrigation Brush Tip and the Acufex Rasp are designed to mechanically debride surfaces during orthopaedic surgical procedures (manual arthroscopic instruments such as rasps have been down classified and are exempted from premarket notification requirements per the Federal Register, Vol. 61, No. 10, published January 16, 1996). The Arthroscopy Pulsed Irrigator (API) Suction

Tip is also substantially equivalent to the currently marketed Davol Arthroscopy Outflow Cannula's (K894990). Both of these devices are designed to allow for the outflow of fluid and debris from the joint space during arthroscopic surgical procedures.

4) **Description and Intended Use of the Device:**

Both the Pneumatic API system and the Battery API system are designed to provide controlled pulsatile irrigation to a joint during arthroscopic surgical procedures. The pulsatile action of the pump irrigation and mechanical debridement of tip brush help to remove blood, tissue debris, loose bodies, and foreign matter from the joint cavity. When connected to a suction source the device's can be used to aspirate fluids and debris from the joint cavity. The device's will be provided as sterile single patient use devices. The major components of the systems are as follows;

4.1 Pneumatic Arthroscopy Pulsed Irrigator System:

The Pneumatic Arthroscopy Pulsed Irrigator (API) system consists of the Davol Simpulse Plus Handle with the API Irrigation/Brush Tip and the API Suction Tip. The Davol Simpulse Plus (K830386) is currently marketed for use in providing pulsatile irrigation during open surgical procedures (e.g. orthopaedic) or for the cleansing of burns/wounds as well as to aspirate fluids and debris from the operative or wound site. The pulsatile action of the pump helps to remove blood, tissue debris, loose bodies and foreign debris from the operative or wound site.

The Pneumatic API System functions by means of a pneumatically activated pump membrane (diaphragm) contained within the pump assembly to generated the pulsating fluid output. The pump membrane is activated by pressure from an air/nitrogen source.

4.2 Battery Arthroscopy Pulsed Irrigator System:

The Battery Arthroscopy Pulsed Irrigator System consists of the Davol Simpulse SOLO Handle with the API Irrigation/Brush Tip and the API Suction Tip. The Davol Simpulse SOLO Handle (K942886) is currently marketed for use in providing pulsatile irrigation during open surgical procedures (e.g. orthopaedic) or for the cleansing of burns/wounds as well as to aspirate fluids and debris from the operative or wound site. The pulsatile action of the pump helps to remove blood, tissue debris, loose bodies and foreign matter from the operative or wound site.

The Battery API system uses a mechanical pumping system to generate the pulsating fluid output. It is powered with four (4) standard AA alkaline batteries with an output amperage of approximately 1.8 amperes, with a voltage of 6 volts, dc (direct current). The batteries power a motor which activates movement of a

bellows pump. The pumping system and power source are housed in the device's handle which will be manufactured from cyrolite (acrylic polymer). The batteries are contained in a battery enclosure within the device's handle.

5) **Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use:**

The 510(k) "Substantial Equivalence Decision Making Process (Detailed)" decision tree was utilized to make a determination of substantial equivalence. The answers to the decision tree questions lead to a determination of substantial equivalence.

1. **Does the New Device Have the Same Indication Statement?**

Yes. The Pneumatic API System, Battery API System, Simpulse Plus Suction Irrigator System and the Simpulse SOLO Suction Irrigator System are jet lavage devices intended to provide controlled powered pulsatile irrigation for the cleansing and debridement of surgical sites (the Simpulse Plus and Simpulse SOLO also have the extended indication of providing irrigation to wound/burns). When connected to a suction source, the devices can be used to aspirate fluids and debris from the surgical site.

The API Irrigation/Brush tip and the Davol Femoral Canal Irrigation Brush Tip are both intended to provide pulsatile irrigation for the cleansing and debridement of orthopaedic surgical sites. In addition ,both of these tips and the Acufex Microsurgical Rasp are intended to provide mechanical debridement of surfaces during orthopaedic surgical procedures.

The API Suction Tip and the Davol Arthroscopic Outflow Cannula are intended to allow for the outflow of fluid and debris from the joint space during arthroscopic surgical procedures.

2. **Does New Device Have Same Technological Characteristics, e.g. Design, Materials, etc.?**

No. The design of the API Irrigation/Brush Tip and the Davol Femoral Canal Irrigation Brush Tip vary in that the dimensions and length of each differ. The Davol Femoral Canal Irrigation Brush Tip has a longer length than the API Irrigation/Brush Tip due to the need for this tip to enter the femoral canal. Since the API Irrigation/Brush Tip is only used in an arthroscopic joint the length of the tip is not required to be as long. Both tips contain bristles on the distal end but the number and size of the bristles differ between

the two tips. There are more bristles on the Femoral Canal Irrigation Brush Tip than on the API Irrigation/Brush Tip since the area surface which is debrided with this tip (femoral canal) is much larger than the surface which is debrided with the API Irrigation/Brush (surfaces within the joint). The height of the bristles on the Femoral Canal Irrigation brush vary from a maximum of .136" and taper down to .053" whereas the height of the API bristles are all .072". The material which the two tips are manufacture from is identical (low density polyethylene). Both of these tips are connected to a handle which allows for irrigation and suction. The design of the Acufex Microsurgical Rasp differs from both the API Irrigation/Brush Tip and the Davol Femoral Canal Irrigation tip in that the tip is knurled and does not contain bristles and it is not connected to a handle which allows for irrigation and suction. The Acufex Microsurgical Rasp is simply used by manual means. The material of the Acufex Microsurgical Rasps differs from the API Irrigation/Brush tip also (stainless steel) due to it's ability to be reused. The Acufex Microsurgical Rasp is provided as a reusable, non-sterile device whereas the API Irrigation/Brush Tip and the Davol Femoral Canal Irrigation tip is provided sterile, single patient use.

The design of the API Suction Tip varies from the Davol Arthroscopy Outflow Cannula in that the length and diameter of the Outflow Cannula are somewhat smaller than the API Suction Tip. The material used to manufacture each of the devices are similar (low density polyethylene and linear low density polyethylene). The principle of operation differs between the two in that the API Suction Tip is connected to a handle (Pneumatic API handle or the Battery API handle) which is connected to the suction source tubing to allow for suction from the joint. The Outflow Cannula is not connected to a handle but rather it is connected directly to the suction source tubing . Both devices are placed directly in the joint cavity to allow for fluid and debris outflow. Both are supplied sterile, single patient use.

There are no differences in the design, materials and principle of operation of the Pneumatic API handle as compared to the Simpulse Plus Suction Irrigator handle and there are no differences in the design, materials and principle of operation of the Battery API handle as compared to the Simpulse SOLO Suction Irrigator handle.

3. Could the New Characteristics Affect Safety or Effectiveness?

No. The new characteristics of the API Irrigation/Brush Tip as compared to the Davol Femoral Canal Irrigation Brush Tip would not affect safety or effectiveness of the device. The different characteristics of the API Irrigation/Brush Tip (connection to a handle which controls irrigation and suction and a bristle tip) as compared to the Acufex Microsurgical Rasp Tip (no connection to a separate handle and a knurl tip) would not affect safety or effectiveness. Both tips are still utilized to mechanically debride surfaces within the joint cavity.

The different characteristics such as length and diameter of the API Suction Tip as compared to the Davol Arthroscopy Outflow Cannula would not affect safety or effectiveness. As with the API Irrigation/Brush tip the difference of connecting through a handle which allows for suction verses direct connection to the suction source tubing and, no connection to a handle, would not affect safety or effectiveness since the suction removal process would still be the same.

There are no new characteristics between the Pneumatic API handle and the Simpulse Plus Suction Irrigator Handle and between the Battery API Handle and the Simpulse SOLO Suction Irrigator.

4. **Are the Descriptive Characteristics Precise Enough to Ensure Equivalence?**

No. The differences between the API Irrigation/Brush Tip and the Davol Femoral Canal Irrigation Brush Tip require that testing be performed to support substantial equivalence in function (i.e. flow rate testing). The descriptive characteristic are enough to ensure equivalence of the API Irrigation/Brush Tip to the Acufex Microsurgical Rasp.

The differences between the API Suction Tip and the Davol Arthroscopy Outflow Cannula also require that testing be performed to support substantial equivalence (i.e. flow rate testing).

The descriptive characteristics of the Pneumatic API handle as compared to the Simpulse Plus Suction Irrigator handle are enough to ensure substantial equivalence. Also, the descriptive characteristics of the Battery API handle as compared to the Simpulse SOLO Suction Irrigator handle are enough to ensure substantial equivalence.

5. **Are Performance Data Available to Assess Equivalence?**

Yes. Laboratory bench testing has been performed to assess the effects of the new characteristics as compared to the devices proposed to be substantially equivalent. This testing included the following:

1) Irrigation flow rate testing of the API Irrigation/Brush Tip as compared to the Davol Femoral Canal Irrigation Brush Tip with each tip

connected to both the Pneumatic API handle and the Battery API handle.

2) Suction flow rate testing of the API Suction Tip connected to both the Pneumatic and Battery handle and suction flow rate testing of the Davol Arthroscopy Outflow Cannula.

3) Pulse frequency and impact pressure of the API Irrigation/Brush Tip as compared to the Davol Femoral Canal Tip with each tip connected to both the Pneumatic API handle and the Battery API handle.

4) Static pressure in a simulated distended joint cavity using the API Irrigation/Brush Tip as compared to the Davol Femoral Canal Irrigation Brush Tip with each tip connected to both the Pneumatic API handle and the Battery API handle and with an outflow cannula open and closed.

Additionally, biocompatibility testing, performed in accordance with the General Program memorandum #G95-1, has been conducted on all materials of the Arthroscopy Pulsed Irrigator Systems which are utilized in the fluid path or which have patient contact.

6. Does Performance Data Demonstrate Equivalence?

Yes. Based upon the results of the laboratory testing, the performance of the Pneumatic API System handle, the Battery API system handle, the API Irrigation/Brush Tip and the API Suction Tip compares favorably to that of the currently marketed Simpulse Plus Suction Irrigator, Simpulse SOLO Suction Irrigator, Davol Femoral Canal Irrigation Brush Tip, and the Davol Arthroscopy Outflow Cannula.

Results from the biocompatibility testing have shown that the materials of the API Systems are suitable for a limited contact, externally communicating device.

CONCLUSION:

Based upon the above information, the Davol Pneumatic and Battery Arthroscopy Pulsed Irrigator Systems (including the API Irrigation/Brush Tip and the API Suction Tip) are substantially equivalent to the Davol Simpulse Plus Suction Irrigator, the Davol Simpulse SOLO Suction Irrigator, the Davol Femoral Canal Irrigation Brush Tip, the Acufex Microsurgical Rasp and the Davol Arthroscopy Outflow Cannula.

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