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1 Device Name

Trade Name of legally marketed devices:	*L-Clip* *Yasargil Aneurysm Clip* *L-Clip Appliers* *Yasargil Aneurysm Clip Appliers*
Trade Name of modified device:	*D-Aneurysm-Clips* *D-Aneurysm Clip Appliers*
Common Name:	*Aneurysm Clip* *Aneurysm Clip Appliers*
Device Classification Name:	*Aneurysm Clip* *Aneurysm Clip Appliers*

2 Classification

Our aneurysm clips and aneurysm clip appliers are classified as follows:

Device:	D-Aneurysm-Clips	D-Aneurysm Clip Appliers
Device description:	Aneurysm clip	Aneurysm clip applier
Medical Specialty:	Neurology	Neurology
Product Code:	HCH	HCI
Regulation Number:	882.5200	882.4175
Device Class:	2	2

3 Substantial Equivalence

The Lazic D-Aneurysm-Clip is substantial equivalent to the already cleared device of Lazic; the L-Clip and the Yasargil Aneurysm Clip.

The Lazic D-Aneurysm Clip Applier is substantial equivalent to the already cleared device of Lazic; the L-Clip Appliers and the Yasargil Aneurysm Clip Appliers.

4 Description of the Device

D-Aneurysm-Clips are available in two principle sizes (Standard and Mini) and several forms of jaws (straight, curved, angled, bayonet, fenestrated, non-fenestrated). Both sizes are available for permanent or temporary occlusion.

D-Aneurysm Clip Appliers are designed to be used with both principle sizes of D-Aneurysm-Clips, Standard and Mini.

4.1 Intended Use/Indications for Use

4.1.1 D-Aneurysm-Clips

Permanent D-Aneurysm-Clips are intended for permanent occlusion of cerebral aneurysms. Temporary D-Aneurysm-Clips are intended for temporary occlusion of intracranial blood vessels and cerebral aneurysms.

4.1.2 D-Aneurysm Clip Appliers

The D-Aneurysm Clip Appliers are intended to be used for holding and applying D-Aneurysm-Clips. The D-Aneurysm Clip Appliers are not compatible with other systems.

4.2 Design

4.2.1 D-Aneurysm-Clip

The D-Clip is manufactured out of three parts, two of those forming the body and one the spring. With D-Clip Appliers it is grasped from the outside to open, close and guide the clip.

4.2.2 D-Aneurysm Clip Appliers

The D-Clip Appliers exists in two versions; a version with double action handles and one version with memory effect. Both versions are applied the same way. Pressing the handle will open the jaw.

4.3 Material

The D-Clip is made of Titanium according to ISO 5832-2 and Titanium alloy Ti6Al4V according to ISO 5832-3.

4.4 Usage/ Application

4.4.1 D-Aneurysm-Clip

Both, the permanent and temporary D-Clips are intended for use by trained surgeons thoroughly familiar with the surgical technique and use of these medical devices.

4.4.2 D-Aneurysm Clip Appliers

The D-Clip Applying Forceps serve for opening and closing the D-Clips. Using the forceps, the aneurysm clip is applied, repositioned or removed in the target tissue. The clip applying forceps have no function of their own and may only be used in combination with the suited D-Clips.

4.5 Technological characteristics

Device	Primary Predicate Device	510(k) Number	510(k) Holder
D-Aneurysm-Clips	L-Clip Yasargil Aneurysm Clip	K081489	Peter Lazic GmbH
D-Aneurysm Clip Appliers	L-Clip Appliers Yasargil Aneurysm Clip Appliers	K081489	Peter Lazic GmbH

4.5.1 Technological characteristics of D-Aneurysm-Clip

Technological characteristics	**---** **Peter Lazic GmbH** D-Aneurysm-Clips	**K081489** **Peter Lazic GmbH** Lazic L-Clips / Yasargil Aneurysm Clips	**Change discussion**
Design	D-clip: Outer application by the applying forceps 	L-clip: Inner application by the applying forceps Yasargil: Outer application by the applying forceps 	Compared to the L-clip the only difference is that the D-clip is applied from the outside. All other design features are identical. For both devices the same spring is used. Meaning they even share a semi-finished good. Compared to the Yasargil clip the D-clip has a similar outer application, but different spring design. **Substantially Equivalent**

Technological characteristics	**---** **Peter Lazic GmbH** Lazic D-Aneurysm-Clips	**K081489** **Peter Lazic GmbH** Lazic L-Clips / Yasargil Aneurysm Clips	**Change discussion**
Closing Force	Mini perm.: 110-130 gms Mini temp.:70-90 gms Standard perm.: 150-180 gms Standard temp.: 90-130 gms Tolerance range: ± 7.5%, measured according to ISO 9713	**L-Clip:** Mini perm.: 110-130 gms Mini temp.:70-90 gms Standard perm.: 150-180 gms Standard temp.: 90-130 gms **Yasargil-Clip:** Mini perm.: 110-130 gms Mini temp.:70-90 gms Standard perm.: 150-200 gms Standard temp.: 90-130 gms Tolerance range: ± 7.5%, measured according to ISO 9713	The closing force of the D-Clip is identical to closing force of the L-Clip and lies in the range of Yasargil-Clip closing force. **Substantially Equivalent**
Materials	Titanium ISO 5832-2 Ti6Al4V ISO 5832-3	**L-Clip:** Titanium ISO 5832-2 Ti6Al4V ISO 5832-3 **Yasargil-Clip:** Ti6Al4V ISO 5832-3 Cobalt alloy Phynox ISO 5832-7	D-Clip is manufactured from the identical materials than the Titanium Versions of the L-Clip and Yasargil Clip. **Substantially Equivalent**
Energy source	No energy source needed	No energy source needed	No difference. **Substantially Equivalent**
Principle of operation	Inside the body of the clip is a spring that creates tension and through this tension the necessary closing force for occlusion. With an applier, the jaws can be opened, closed and guided for occlusion.	Inside the body of the clip is a spring that creates tension and through this tension the necessary closing force for occlusion. With an applier, the jaws can be opened, closed and guided for occlusion.	No difference. **Substantially Equivalent**

4.5.2 Technological characteristics of D-Aneurysm Clip Applier

Technological characteristics	**---** **Peter Lazic GmbH** Lazic D-Aneurysm Clip Appliers	**K081489** **Peter Lazic GmbH** Lazic L-Aneurysm Clip Appliers / Yasargil Aneurysm Clip Appliers	**Change discussion**
Design	One version with double action handles and one with memory effect.	One version with double action handles and one with memory effect.	Versions with double action handles and with memory effect of the D-Clip Appliers have identical shanks compared to those of the L-Clip and the Yasargil Clip. The difference of the three Appliers lies in the jaw design. When the shanks of the D-Clip Appliers and the Yasargil Clip Appliers are compressed, the jaws are closing making the clip open up. When the shanks of the L-Clip Appliers are compressed the jaws are opening up, making the clip open up. **Substantially Equivalent**
Materials	1.4021 / ASTM A 276 / AISI 420A; 1.4305 / AISI 303; 1.4310 / AISI 301; 3.7165 / ASTM F 136 / ISO 5832-3; Nitinol / ASTM F0263-05	1.4021 / ASTM A 276 / AISI 420A; 1.4305 / AISI 303; 1.4310 / AISI 301; 3.7165 / ASTM F 136 / ISO 5832-3; Nitinol / ASTM F0263-05	D-Clip Appliers are manufactured from the identical materials than the Titanium Versions of the L-Clip and Yasargil Clip Appliers. **Substantially Equivalent**
Energy source	No energy source needed	No energy source needed	No differences **Substantially Equivalent**

Technological characteristics	**---** **Peter Lazic GmbH** Lazic D-Aneurysm Clip Appliers	**K081489** **Peter Lazic GmbH** Lazic L-Aneurysm Clip Appliers / Yasargil Aneurysm Clip Appliers	**Change discussion**
Applying Technique	Compressing clip shanks to open the clip from outer side of shanks. 	**L-Clip Appliers:** Compressing clip shanks to open the clip from inside of shanks. **Yasargil Aneurysm Clip Appliers:** Compressing clip shanks to open the clip from outer side of shanks. 	The applying technique of D-Clip Appliers and Yasargil Clip Appliers is identical. Compressing the clip shanks closes the jaws and opens the D-clip respective Yasargil Clip. Compressing the clip shanks of the L-Clip Appliers opens the jaws and that opens the L-Clip. **Substantially Equivalent**

5 Performance Standards

5.1 D-Aneurysm-Clips

Test	Test Method Summary	Results
Microbiological performance qualification of gamma radiation sterilization	10 samples of the worst case clips were tested. The verification dose was determined based on the average bioburden of three lots as 5,2±0,52kGy. The 10 samples were gamma irradiated.	An average bioburden of 2,0 cfu/sample was determined after sterilization. The tests indicated that the microbial contamination was inactivated by the irradiation of 5,40 kGy ± 3,7 %. Therefore, the gamma irradiation method ensures effective conditions with a sterility assurance level (SAL) $<10^{-6}$ for the sterilization of the devices by application of a minimum dose of 25 kGy. The tests were conducted on a worst case clip. The worst case analysis covers the predicate device as well as the D-Clip. The results show that it is possible to sterilize the D-Clip with an identical sterilization dose than the predicate device.
Validation of the sterile barrier system (SBS))	A validation of the sterile barrier system has been conducted by the responsible service provider. A basic stability study of the empty SBS as well as stability studies and performance testing of the SBS with products was conducted.	The requirements imposed on microbial barrier properties for the basic SBS were met successfully for the packaging material. Shelf life of the sterile barrier system after 5 years accelerated aging was confirmed successfully.
MRI Safety	The devices had been tested in a static magnetic field of 1,5 and 3-Tesla and a maximum spatial gradient magnetic field of 4,000-Gaus/cm.	The testing demonstrated that the D-Clip and the predicate device are MR Conditional. They will not present an additional hazard or risk to a patient undergoing an MRI procedure in a static magnetic field of 1.5- Tesla and 3-Tesla, with a maximum spatial gradient magnetic field of 4,000-Gauss/cm. A maximum whole body averaged specific absorption rate of 2-W/kg for 15 minutes of scanning in the Normal Operating Mode was measured. These parameters are equivalent for the D-Clip and the L-Clip. The D-Clip is expected to produce a maximum temperature rise of 1,7°C after 15-minutes of continuous scanning. The L-Clip is expected to produce a maximum temperature rise of 1,8°C after 15-minutes of continuous scanning. The D-Clip extends approximately 10-mm from this implant when imaged using a gradient echo pulse

		sequence and a 3-Tesla MR system, while the L-Clip extends approximately 15-mm. The results for the D-Clip outperform those for the predicate device.
LAL endotoxin test	The samples were rinsed with sterile, pyrogen free water according to the product- and method-specific validation. Then, the rinsing fluids were investigated for the presence of endotoxins with the quantitative LAL endotoxin test. Sterile, pyrogen free water was used as negative control, FDA proved endotoxin standard as positive control.	Endotoxins were not detected in the rinsing fluids of the investigated samples. The test has been performed on the predicate device. Since the devices are manufactured with similar manufacturing processes and identical materials the results are deemed applicable.
Degradation of closing force tests	The closing force of the clip shall be measured before and after 10 maximum opening of the clip with the recommended applier. The reduction of the closing force shall be less than 5% of the nominal closing force.	The tested D-Clips did fulfill the requirements of ISO 9713. The test results of the L-Clips and the Yasargil Clips fulfilled the requirements as well. The closing force is deemed equivalent.

5.2 D-Aneurysm Clip Appliers

Test	**Test Method Summary**	**Results**
Microbiological efficiency control of the automated cleaning and disinfection method	For determination of the cleaning efficiency selected reference products were contaminated with "British Soil" containing spores of Bacillus atrophaeus. For determination of the disinfection efficiency, selected reference products were contaminated with a suspension of the high-resistant test organism Mycobacterium terrae. Then, according to the instructions of the sponsor the automated cleaning and disinfection method was performed on three contaminated reference products. Afterwards, the reduction of the test organisms was determined.	A worst-case selection has been conducted identifying several critical components. A dummy device including the critical components was manufactured and used for all reprocessing validations. The concentration of the used test organisms Bacillus atrophaeus was reduced by the automated cleaning method of at least 5.2 log steps. The concentration of the used test organism Mycobacterium terrae was reduced of at least 6.8 log steps. The tests had been conducted with the predicate device. The before described worst-case dummy has more or identical disadvantageous properties with regard to product geometry and surface structure. Therefore the D-Clip appliers are deemed to be able to be cleaned and disinfected equivalent to the predicate device.

Microbiological efficiency control of the manual cleaning and disinfection method	For determination of the cleaning efficiency selected reference products were contaminated with "British Soil" containing spores of Bacillus atrophaeus. For determination of the disinfection efficiency, selected reference products were contaminated with a suspension of the high-resistant test organism Mycobacterium terrae. Then, according to the instructions of the sponsor the manual cleaning and disinfection method was performed on three contaminated reference products. Afterwards, the reduction of the test organisms was determined.	Visible remains of the contamination medium were not detected on the reference devices after performance of the manual cleaning method. The concentration of the used test organisms Bacillus atrophaeus was reduced by the manual cleaning method of at least 4.8 log steps. The concentration of the used test organism Mycobacterium terrae was reduced of at least 5.3 log steps. The tests had been conducted with the predicate device. The before described worst-case dummy has more or identical disadvantageous properties with regard to product geometry and surface structure. Therefore the D-Clip appliers are deemed to be able to be cleaned and disinfected equivalent to the predicate device.
Microbiological efficiency control of steam sterilization	Three qualification runs with three inoculated test samples each were conducted. The first and third run was conducted with sterilization temperature 121°C, exposure time 10min (half cycle) and the second run with sterilization temperature 132°C, exposure time 1,5min (half cycle). For each qualification run one non-exposed process challenge device per type was used as control for spore viability. For inoculation the most difficult parts for steam access were used. The Type A1 challenge devices were inoculated at the joint of the forceps, at the annular gap of the shaft and at the gap between spring and handle. The Type A2 challenge devices were inoculated at the joint of the forceps, at the annular gap of the shaft and at the joint of the handle. The Type A3 challenge devices were inoculated at the front, the central and the back of the cross armed joint.	All tested devices in three independent half cycle qualification runs were free of microbial growth. The conducted tests indicate that the products of the product group Applying Forceps of Peter Lazic can be steam-sterilized with a sufficient spore log reduction of >12 by use of standard sterilization parameters (fractioned vacuum procedure, 121°C, 20 min, and 134°C, 4min). The tests had been conducted with the predicate device. The before described worst-case dummy has more or identical disadvantageous properties with regard to steam access, steam permeability and product geometry than the D-Clip appliers. Therefore the D-Clip appliers are deemed to be able to be sterilized equivalent to the predicate device.
Bending test Memory material in straight condition at the beginning of use/ -without wash-out and cleaning cycles-	The test was determined to show via three point bending procedure how much force is necessary to bend the shaft. The tests had been conducted on the raw material with mechanical force. First the force to bend the product was measured as well as the maximum radius and angle. Then the material was bend 100 times,	About 40 N were necessary to deform the shaft, meaning it takes force to deform the shaft, but the shaft can be deformed without much effort. The material can be bend by hand without much effort. The test also shows that the material properties have not changed after a certain time. The force required to bend the shaft was in a similar range after

	measuring the bending force again after 100 bendings.	100 bends. This means that bending has no effect on the material and its properties. Therefore, the material has no negative effect on the device.
Defining the bending cycles to possible function restrictions	The aim of the test is to find out whether applying forceps with memory shaft shows possible functional limitations after bending some times. 10 applying forceps are bent several times without heating and regenerating the shaft in between. The bending is done manually and without exact determination of the bending angle, as it is the case in operations. The procedure is as follows, the appliers are checked for functions in their original steps with zero bendings. Then the shaft is bent over 90° and the appliers are checked for their functions. In the next step the shaft is straightened, and the appliers are checked for their functions. 30 repetitions are performed (15 times 90° bending, 15 times straightening)	The results were positive without exception. After 30 repetitions all applying forceps were still functioning as intended. The bending did not have an influence on the function of the applier. They still fulfilled the technical requirements.
Behavior of the D-Clip Applying forceps after repeated use and reprocessing	For this test 10 D-Clips appliers were produced. In the test the use and reprocessing of the device was simulated. Therefore, the Items were bend 10 times, then cleaned in an ultrasonic bath (simulating a manual cleaning) and then sterilized at 134°C for 12 minutes. This procedure was performed 100 times.	All 10 tested Memory D-Aneurysm-Clip Appliers showed full function after the maximum tested 100 cycles. All Memory-Clip Appliers were tested according To the testing for product release and fulfilled the specification. Therefore, we can tell that the bending of the shaft within 100 times max. bending does not have effects on the function of the D-Clip Memory applier.

6 Sterilization

Lazic's D-Aneurysm-Clips are available in sterile conditions. Lazic's D-Aneurysm Clip Appliers are available in non-sterile conditions only.

7 Conclusion

The modification of Lazic's D-Aneurysm-Clips raises no new questions of safety and effectiveness. It combines the design of the L-Clip with the application of the Yasargil Aneurysm Clip. The same applies to Lazic's D-Aneurysm Clip Appliers.

Therefore, the D-Aneurysm-Clips and the D-Aneurysm Clip Appliers are substantially equivalent to the predicate devices.