Food and Drug Administration
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October 26, 2015

Olympus Winter & Ibe Gmbh
% Graham Baillie
Manager, Regulatory Affairs
Gyrus Acmi, Inc.
136 Turnpike Rd.
Southborough, Massachusetts 01772

Re: K152092
Trade/Device Name: Electrodes for resection in saline (WA22302S, WA22306S, WA22332S, WA22351S, WA22355S, WA22503S, WA22507S, WA22521S, WA22523S, WA22537S, WA22538S, WA22539S, WA22557S, WA22558S, and WA22559S)

Monopolar Electrodes (WA22201S, WA22202S, WA22203S, WA22210S, WA22211S, WA22221S, WA22222S, WABD09MS, WABD10MS, WACL21MS, WACL27MS, WACL28MS, WALP03MS, WALP04MS, WALP06MS, WALP08MS, WALP13MS, WALP14MS, WALP31MS, WALP35MS, WAND18MS, WAND20MS, WARL16MS, WARL23MS, WARL33MS, WARN25MS)

Slim Resection Electrodes (WA47050S, WA47051S, WA47052S, WA47053S, WA47054S, WA47055S, WA47056S)

Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: FAS, FJL, HIH
Dated: July 27, 2015
Received: July 28, 2015

Dear Graham Baillie:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)* K152092

Device Name
Electrodes for resection in saline (WA22302S, WA22306S, WA22332S, WA22351S, WA22355S, WA22503S, WA22507S, WA22521S, WA22523S, WA22537S, WA22538S, WA22539S, WA22557S, WA22558S, and WA22559S)

Indications for Use *(Describe)*
Electrodes are part of a resectoscope system for endoscopic diagnosis and treatment in urological applications. Cutting, ablation, resection, vaporization and coagulation with HF current.

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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)* K152092

Device Name
Monopolar Electrodes (WA22201S, WA22202S, WA22203S, WA22210S, WA22211S, WA22221S, WA22222S, WABD09MS, WABD10MS, WACL21MS, WACL27MS, WACL28MS, WALP03MS, WALP04MS, WALP06MS, WALP08MS, WALP13MS, WALP14MS, WALP31MS, WALP35MS, WAND18MS, WAND20MS, WARL16MS, WARL23MS, WARL33MS, WARN25MS)

Indications for Use *(Describe)*
General intended use

Urology
Electrodes are part of a resectoscope system for endoscopic diagnosis and treatment in urological applications. Cutting, ablation, resection, vaporization and coagulation with HF current.

Gynecology
Electrodes are part of a resectoscope system for endoscopic diagnosis and treatment in gynecological applications. The general indications include transcervical resection, vaporization, ablation, cutting and coagulation of tissue in the uterus in non-conducting irrigation fluid.

The following products are not intended to be used in gynecology: WA22202S, WA22203S, WA22222S, WABD10MS, WALP06MS, WALP08MS

Specific intended use

Gynecology
- Transcervical diagnosis and treatment (resection, vaporization, ablation, biopsy, cutting and coagulation) of intrauterine myomas, intrauterine polyps, synechias and endometrium
- Lysis of intrauterine septa
- Endometrial ablation

The following products are not intended to be used in gynecology: WA22202S, WA22203S, WA22222S, WABD10MS, WALP06MS, WALP08MS

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)* K152092

Device Name
Slim Resection Electrodes (WA47050S, WA47051S, WA47052S, WA47053S, WA47054S, WA47055S, WA47056S)

Indications for Use *(Describe)*
General intended use

Urology
Electrodes are part of a resectoscope system for endoscopic diagnosis and treatment in urological applications. Cutting, ablation, resection, vaporization and coagulation with HF current.

The following product is not intended to be used in urology: WA47056S

Gynecology
Electrodes are part of a resectoscope system for endoscopic diagnosis and treatment in gynecological applications. The general indications include transcervical resection, vaporization, ablation, cutting and coagulation of tissue in the uterus in non-conducting irrigation fluid.

Specific intended use

Gynecology
- Transcervical diagnosis and treatment (resection, vaporization, ablation, biopsy, cutting and coagulation) of intrauterine myomas, intrauterine polyps, synechias and endometrium
- Lysis of intrauterine septa
- Endometrial ablation

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)

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510(k) Summary of Safety and Effectiveness
July 21, 2015

1. General Information

Manufacturer:	Olympus Winter & Ibe GmbH Kuehnstr. 61 22045 Hamburg Germany Establishment Registration Number: 9610773
Official Correspondent:	Graham A.L. Baillie Manager, Regulatory Affairs Gyrus ACMI, Inc. 136 Turnpike Rd. Southborough, MA 01772-2104 Phone: 508.804.2738 Fax: 508. 804.2624 Email: Graham.baillie@olympus-osta.com
Establishment Registration No	3003790304

2. Device Identification

Common Name:	- Electrode, Electrosurgical, Active, Urological
Regulation Number:	876.4300
Classification	- Endoscopic electrosurgical unit and accessories
Device Class:	II
Product Code:	FAS / HIH / FJL
Review Panel:	Gastroenterology/Urology
Proprietary/Trade Name:	Electrodes for resection in saline (WA22302S, WA22306S, WA22332S, WA22351S, WA22355S, WA22503S, WA22507S, WA22521S, WA22523S, WA22537S, WA22538S, WA22539S, WA22557S, WA22558S, and WA22559S), Monopolar Electrodes (WA22201S, WA22202S, WA22203S, WA22210S, WA22211S, WA22221S, WA22222S, WABD09MS, WABD10MS, WACL21MS, WACL27MS, WACL28MS, WALP03MS, WALP04MS,

WALP06MS, WALP08MS, WALP13MS, WALP14MS, WALP31MS, WALP35MS, WAND18MS, WAND20MS, WARL16MS, WARL23MS, WARL33MS, WARN25MS)

Slim Resection Electrodes (WA47050S, WA47051S, WA47052S, WA47053S, WA47054S, WA47055S, WA47056S)

3. Predicate Devices

For each electrode model the respective predicate device was chosen from the following predicate 510(k)s:

510(k) No.	Name	Predicate Model No.	Product code / Reg No.
K897003	Olympus Hysteroresectoscope	A2184, A2189, A2193, A4516	HIH / 884.1690
K903323	Resectoscope Loops	A2183S, A2184S, A2185S, A2189S, A2193S, A2195S, A2203S, A2204S, A2205S, A4513S, A4514S, A4515S, A4513US, A4514US	KNS / 876.4300
K931764	HF Resection Electrode, Loop w/runner Hyster/Acces	A2186, A2228	HIH / 884.1690
K954488	Roller Electrode	A2158S	HIH / 884.1690
K931763	HF-Resection Electrode, Loop w/runner Hyster/Acces	A2186	FAS / 876.4300 FJL / 876.1500
K100275	Resection Button Electrode for Plasma Vaporization, HF-Resection Electrode Loops and Band	WA22302D, WA22306D, WA22332D, WA22351C, WA22355C, WA22503D, WA22507D, WA22521C, WA22523C, WA22537D, WA22538C, WA22539D, WA22557C, WA22558C	FAS / 876.4300 GEI / 878.4400

These predicates have not been subject to a design-related recall.

No reference devices were used in this submission.

4. Product Description

The Olympus Resection Electrodes that are subject to this submission are either monopolar or for application in saline. The main difference between monopolar electrosurgery and electrosurgery in saline is that while in monopolar electrosurgery a neutral electrode is required, whereas in electrosurgery in saline the (neutral) return electrode is part of the surgical device.

Depending on the characteristics of electrical current, which is provided by the electrosurgical generator, electrosurgery can be used for coagulation, vaporisation and cutting.

The subject HF-Resection Electrodes consist of an active tip, PTFE color code identification, an insulator between the electrode and electrode tube, a guiding tube, telescope clip and arm (shaft).

The design and dimensions of the electrodes vary to accommodate various procedural conditions. The active tips of the various electrodes may consist of loops, bands, rollers, needles or buttons.

All subject Resection Electrodes are **single-use** electrodes and are delivered **sterile**.

1. Subject electrodes for Hystero-Resectoscope System with 4mm Telescope (OES Pro)	
1.1 Monopolar electrodes standard length	
WA22201S	HF-resection electrode, loop 24 Fr., 0.35 wire, 12°/16°
WA22210S	HF-resection electrode, loop, 24 – 28 Fr., 0.2 wire, 12°/16°
WALP03MS	HF-resection electrode, loop 24 Fr., 0.35 wire, 12° - 30°
WALP04MS	HF-resection electrode, loop, 24 – 28 Fr., 0.2 wire, 12° - 30°
WARN25MS	HF-resection electrode, loop with runner, 24 Fr., 12° - 30°
WALP13MS	HF-resection electrode, angled loop, 24 - 28 Fr., 0.35 wire, 12° - 30°
WALP14MS	HF-resection electrode, angled loop, 24 - 28 Fr., 0.2 wire, 12° - 30°
WARL16MS	HF-resection electrode, roller, 24 - 28 Fr., 12° - 30°
WARL23MS	HF-resection electrode, large roller, 24 - 28 Fr., 12° - 30°
WACL27MS	HF-resection electrode, cylinder, 24 - 28 Fr., 12° - 30°
WAND18MS	HF-resection electrode, needle 90°, 24 - 28 Fr., 12°/16°
WAND20MS	HF-resection electrode, angled needle, 24 - 28 Fr., 12° - 30°
WACL21MS	HF-resection electrode, cylinder with grooves, 24 - 28 Fr., 12° - 30°
WA22211S	HF-resection electrode, loop with runner, 24 Fr., 12°/16°
WA22221S	HF-resection electrode, band 24 Fr., 12°/16°
WABD09MS	HF-resection electrode, band 24 Fr., 12° - 30°
WACL28MS	HF-resection electrode, cylinder with spikes, 24 - 28 Fr., 12° - 30°
1.2 Electrodes for resection in saline - standard length (Urology only)	
WA22302S	HF-resection electrode, loop, 24 Fr., 0.2 wire, standard, 12°/16°
WA22503S	HF-resection electrode, large loop, 24 Fr., 0.2 wire, 12°/16°
WA22306S	HF-resection electrode, loop, 24 Fr., 0.2 wire, standard, 12° - 30°
WA22507S	HF-resection electrode, large loop, 24 Fr., 0.2 wire, 12° - 30°
WA22521S	HF-resection electrode, band, 24 Fr., standard, 12°/16°

WA22523S	HF-resection electrode, band, 24 Fr., standard, 12° - 30°
WA22332S	HF-resection electrode, angled loop, 24 Fr., 0.2 wire, standard, 12° - 30°
WA22351S	HF-resection electrode, roller, 24 Fr., 12° - 30°
WA22355S	HF-resection electrode, angled needle, 24 Fr., 12° - 30°
WA22557S	HF-resection electrode, button, 24 Fr., 12° - 30°
2. Subject electrodes for long Resectoscope OES Pro with 4mm Telescope	
2.1 Monopolar electrodes long	
WALP31MS	HF-resection electrode, long loop, 24 Fr., 12°
WARL33MS	HF-resection electrode, long roller, 24 - 28 Fr., 12° - 30°
WALP35MS	HF-resection electrode, long angled loop, 24 - 28 Fr., 12° - 30°
2.2 Electrodes for resection in saline - long (Urology only)	
WA22537S	HF-resection electrode, long loop, 24 Fr., 0.2 wire, standard, 12°
WA22538S	HF-resection electrode, long roller, 24 Fr., 12° - 30°
WA22539S	HF-resection electrode, long angled loop , 24 Fr., 0.2 wire, standard, 12° - 30°
3. Subject electrodes for Hystero-Resectoscope System with 3mm Telescope	
3.1 Monopolar slim electrodes standard length	
WA47050S	HF-resection electrode, loop, 22.5 Fr., 0.35 wire, 12°
WA47051S	HF-resection electrode, angled loop, 22.5 Fr., 0.35 wire, 12°
WA47052S	HF-resection electrode, roller, 22.5 Fr., 12° and 30°
WA47053S	HF-resection electrode, cylinder, 22.5 Fr., 12° and 30°
WA47054S	HF-resection electrode, angled needle, 22.5 Fr., 12°
WA47055S	HF-resection electrode, cylinder with grooves, 22.5 Fr., 12° and 30°
WA47056S	HF-resection electrode, cylinder with spikes, 22.5 Fr., 12° and 30° (gyn only)
4. Subject electrodes for urology-only	
4.1 Monopolar electrodes standard length (Urology only)	
WA22202S	HF-resection electrode, loop 26 Fr., 0.35 wire, 12°/16°
WA22203S	HF-resection electrode, loop 28 Fr., 0.35 wire, 12°/16°
WA22222S	HF-resection electrode, band 26 Fr., 12°/16°
WABD10MS	HF-resection electrode, band 26 Fr., 12° - 30°
WALP06MS	HF-resection electrode, loop 26 Fr., 0.35 wire, 12° - 30°
WALP08MS	HF-resection electrode, loop 28 Fr., 0.35 wire, 12° - 30°
4.2 Electrodes for resection in saline - standard length (Urology only)	
WA22558S	HF-resection electrode, TUEB angled loop , 24 Fr., 12° - 30°
WA22559S	HF-resection electrode, TUEB loop, 24 Fr., 12° - 30°

5. Indications for Use

The subject device resection electrodes have essentially the same intended use as the predicate resection electrodes (K897003, K903323, K931763, K931764, K954488, or K100275, respectively).

Subject Monopolar Electrodes
(WA22201S, WA22202S, WA22203S, WA22210S, WA22211S, WA22221S, WA22222S, WABD09MS, WABD10MS, WACL21MS, WACL27MS, WACL28MS, WALP03MS, WALP04MS, WALP06MS, WALP08MS, WALP13MS, WALP14MS, WALP31MS, WALP35MS, WAND18MS,

WAND20MS, WARL16MS, WARL23MS, WARL33MS, WARN25MS)

General intended use
Urology
Electrodes are part of a resectoscope system for endoscopic diagnosis and treatment in urological applications. Cutting, ablation, resection, vaporization and coagulation with HF current.

Gynecology
Electrodes are part of a resectoscope system for endoscopic diagnosis and treatment in gynecological applications. The general indications include transcervical resection, vaporization, ablation, cutting and coagulation of tissue in the uterus in non-conducting irrigation fluid.

The following products are not intended to be used in gynecology:
WA22202S, WA22203S, WA22222S, WABD10MS, WALP06MS, WALP08MS

Specific intended use
Gynecology

- Transcervical diagnosis and treatment (resection, vaporization, ablation, biopsy, cutting and coagulation) of intrauterine myomas, intrauterine polyps, synechias and endometrium
- Lysis of intrauterine septa
- Endometrial ablation

The following products are not intended to be used in gynecology:
WA22202S, WA22203S, WA22222S, WABD10MS, WALP06MS, WALP08MS

Subject Electrodes for Resection in Saline
(WA22302S, WA22306S, WA22332S, WA22351S, WA22355S, WA22503S, WA22507S, WA22521S, WA22523S, WA22537S, WA22538S, WA22539S, WA22557S, WA22558S, WA22559S)

Electrodes are part of a resectoscope system for endoscopic diagnosis and treatment in urological applications. Cutting, ablation, resection, vaporization and coagulation with HF current.

Slim Electrodes
(WA47050S, WA47051S, WA47052S, WA47053S, WA47054S, WA47055S, WA47056S)

General intended use
Urology
Electrodes are part of a resectoscope system for endoscopic diagnosis and treatment in urological applications. Cutting, ablation, resection, vaporization and coagulation with HF current.

The following product is not intended to be used in urology: WA47056S

Gynecology
Electrodes are part of a resectoscope system for endoscopic diagnosis and treatment in gynecological applications. The general indications include transcervical resection, vaporization, ablation, cutting and coagulation of tissue in the uterus in non-conducting irrigation fluid.

Specific intended use
Gynecology

- Transcervical diagnosis and treatment (resection, vaporization, ablation, biopsy, cutting and coagulation) of intrauterine myomas, intrauterine polyps, synechias and endometrium
- Lysis of intrauterine septa
- Endometrial ablation

6. Comparison of Technological characteristics

At a high level, the subject and predicate devices are based on similar technological principles with similar elements:

- Resection electrodes consisting of an active (distal) tip, PTFE color code identification at the distal and proximal ends, an insulator between the electrode and electrode tube, a stabilizing (guiding) tube, and arm (shaft)
- Used in combination with a resectoscope system
- Like the predicate electrodes, the subject device resection electrode series features loops, bands, needles, rollers, and a button as active tip shapes
- Utilizing either monopolar mode of ablation or for resection in saline (dependent on model)
- Respectively identical or similar outer dimensions
- Design changes of the electrodes are minor and do not negatively impact safety or effectiveness of the subject devices
- The same or similar materials in patient contact are used in predicate and subject device and have all been successfully tested for biocompatibility.

As stated above, the subject and predicate devices have similar design characteristics and performance specifications. The primary technological differences between the subject and predicate devices are related to the patient contacting materials. These minor differences, however, do not raise different questions of safety or effectiveness. As demonstrated in the non-clinical testing (e.g., biocompatibility), the different technological characteristics do not affect the safety and effectiveness of the subject devices.

7. Performance Data

The following performance data was provided in support of the substantial equivalence determination. All standards applied are FDA recognized international standards.

Biocompatibility testing
All biocompatibility testing has been conducted according to ISO 10993-1 Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing. Additionally, the FDA guidance "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" was followed.

Testing included the following tests:

- Cytotoxicity
- Irritation
- Sensitization
- Chemical Analysis
- Biological-toxicological evaluation

Electrical safety and electromagnetic compatibility (EMC)
Electrical Safety was tested according to

AAMI/ANSI ES 60601-1:2005 + A1:2012, C1:2009 and A2:2010	Medical Electrical Equipment - Part 1.1 General requirements for safety and essential performance.
AAMI/ANSI/IEC 60601-2-2 2009	Medical Electrical Equipment - Part 2-2: Particular Requirements for the Basic Safety And Essential Performance of High Frequency Surgical Equipment and High Frequency Surgical Accessories
IEC 60601-2-18:2009	Medical electrical equipment - Part 2-18: Medical Electrical Equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment.

Electromagnetic compatibility (EMC) testing according to IEC 60601-1-2 and IEC 60601-2-2 was conducted for the resectoscope system, but not for the standalone Resection Electrodes. EMC testing demonstrates that the compatible resectoscope system complies with all requirements of IEC 60601-1-2 and IEC 60601-2-2. Since all resection electrodes are made of similar conductive materials, there is no reason to expect that different electrodes would affect the electrical properties of the resectoscope system. They do not contain

any electrical components that can be influenced by electromagnetic emission as well as electrostatic discharge.

Thermal Safety
Tested according to AAMI/ANSI/IEC 60601-2-2 2009, Medical Electrical Equipment - Part 2-2: Particular Requirements for the Basic Safety and Essential Performance of High Frequency Surgical Equipment and High Frequency Surgical Accessories.

Clinical Evaluation
Clinical and animal studies were not necessary.
A clinical evaluation has been conducted containing a comprehensive literature review.

Software
Not applicable as the Resection Electrodes do not contain any software.

Performance Testing Bench
Conducted tests include mechanical and electrical performance testing, resection/coagulation testing, durability testing, and transport/packaging testing.

8. Sterilization and Shelf Life

Sterilization is performed according to ISO 11135 and packaging conforms with AAMI ANSI ISO 11607-1:2006. The EtO sterilization cycle has been validated.

A sterility assurance level (SAL) of 10^{-6} was reached during validation and will be used for routine sterilization in compliance with regulations in force for sterile medical devices.

The EtO residuals are within the limits after tunnel degassing time.

Shelf Life testing was conducted, including performance testing and package integrity testing, to support a shelf life of 5 years for the resection electrodes.

9. Conclusion

The performance data support the safety of the device and demonstrate that the subject devices comply with the intended use as specified.

In summary, we believe the Resection Electrodes are substantially equivalent with the predicate devices with respect to the general design approach, function, and the intended use. The Resection Electrodes raise no new concerns of safety or effectiveness when compared to the predicate devices.