December 1, 2023

Medcaptain Life Science Co., Ltd.
Alan Tao
Official Correspondent
601, Building C, Jinweiyuan Industrial Park, Pingshan
District
Shenzhen, Guangdong 518118
China

Re: K230528
Trade/Device Name: Extension Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: October 31, 2023
Received: November 1, 2023

Dear Alan Tao:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Porsche Bennett
For David Wolloscheck, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K230528

Device Name
Extension Set

Indications for Use *(Describe)*
Extension Sets are intended to be used with a vascular access device for direct injection, intermittent infusion, continuous infusion or aspiration. The Extension Sets may be used with power injector procedures to a maximum pressure of 200 kPa (2 bar).

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- K230528

I. Submitter/510(k) Holder

Submission:	Traditional 510(k) Premarket Notification
Submitter:	MEDCAPTAIN LIFE SCIENCE CO., LTD.
Address:	601, Building C, Jinweiyuan Industrial Park, Pingshan District, Shenzhen, Guangdong, CN 518118.
Contact Person:	Alan Tao
Telephone:	+86-755-28380626
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Email:	alan.tao@medcaptain.com
Date prepared:	December 1, 2023

II. Device

Device Trade Name:	Extension Set
Device Common Name:	Intravascular Administration Set
Regulatory Name:	Intravascular Administration Set
Regulation Number:	21 CFR 880.5440
Product Code:	FPA
Product Code Name:	Set, Administration, Intravascular
Regulatory Class:	Class II
Review Panel:	General Hospital

III. Predicate Devices

The Extension Set is substantially equivalent to the following legally marketed predicate device:
Extension Set (K153293, B.Braun Medical Inc.) cleared on April 6, 2016.

Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA

IV. Device Description

The subject device, Extension sets are single use, sterile, non-pyrogenic, add-on devices used for direct injection, intermittent infusion, continuous infusion or aspiration. The device is to connect the infusion device through the luer lock connector to add length and provide clamping capacities, or added to an intravascular catheter

hub as a conduit for flow to and from the catheter. It is available in various lengths and tube dimensions, and may be comprised of various generic components such as connectors, clamps, flow regulators, filters, check valves and needleless injection ports. It can be used for gravity infusion and pressure infusion with pressure up to a maximum of 200 kPa (2 bar).

V. Indications for Use

Extension Sets are intended to be used with a vascular access device for direct injection, intermittent infusion, continuous infusion or aspiration. The Extension Sets may be used with power injector procedures to a maximum pressure of 200 kPa (2 bar).

VI. Comparison of Technological Characteristics with the Predicate Device

The subject device, Extension Set, and the predicate device, Extension Sets (K153293), are substantially equivalent in that these devices have the same intended use and patient contact category/duration, similar indications for use, patient population and technological characteristics. They have the same characteristics including technology or design of PVC tube, luer lock connector, slide clamp, check valve, filters, pinch clamp and needle free injection port, etc. The differences between the subject device and the predicate device include the maximum pressure resistance, components of anti-siphon valve and protective cap, and materials. The maximum pressure of the subject device is less than that of the predicate device, which can be acceptable in clinical use to achieve the intended use. Performance testing has been conducted on the anti-siphon valve and protective cap components and have been demonstrated to meet the requirements. The materials of subject device are biocompatible based on biocompatibility tests. The differences between the subject and predicate device do not raise any new or different questions of safety and/or effectiveness.

Similarities and differences in technology characteristics are captured in the substantial equivalence comparison between the subject device and the predicate device, which are provided in Table 1.

Table 1 Substantial Equivalence Comparison

Description	Extension Sets (Predicate device)	Extension Set (Subject device)	Comparison to predicate device
510(k) Number	K153293	K230528	N/A
Regulation Number	21 CFR 880.5440	21 CFR 880.5440	Identical
Regulatory Name	Intravascular Administration Set	Intravascular Administration Set	Identical
Product Code	FPA	FPA	Identical

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Description	Extension Sets (Predicate device)	Extension Set (Subject device)	Comparison to predicate device
Regulatory Class	Class II	Class II	Identical
Intended Use	B.Braun Extension Sets are intended for direct injection, intermittent infusion, continuous infusion or aspiration.	Extension Sets are intended for direct injection, intermittent infusion, continuous infusion or aspiration.	Identical
Indications for use	B.Braun Extension Sets may be used for direct injection, intermittent infusion, continuous infusion or aspiration of fluids, medications, blood and blood products. Select sets may be used with power injector procedures to a maximum pressure of 400 psi at a maximum flow rate of 15mL per second. B.Braun's optional stabilization component on an extension set is intended to provide stability to the patient connector, which is attached to an intravascular catheter. B.Braun Extension Sets may be used for any patient population.	Extension Sets are intended to be used with a vascular access device for direct injection, intermittent infusion, continuous infusion or aspiration. The Extension Sets may be used with power injector procedures to a maximum pressure of 200 kPa (2 bar).	Different Difference does not raise new or different questions of safety or effectiveness. See Justification 1
Mode of Fluid Delivery	Gravity, or power injection to a maximum pressure of 400 psi.	Gravity, or pressure injection to a maximum pressure of 200kPa.	Different Difference does not raise new or different questions of safety or effectiveness. See Justification 2
Prescription/ Over-the-Counter	Prescription	Prescription	Identical
Patient Population	Any patient population	Adults and pediatrics	Different

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Description	Extension Sets (Predicate device)	Extension Set (Subject device)	Comparison to predicate device
			Difference does not raise new or different questions of safety or effectiveness. See Justification 3
Patient Contact category/duration	Externally communicating, Blood path indirect, prolonged exposure	Externally communicating, Blood path indirect, prolonged exposure	Identical
Device Components	Configured: PVC tubing, Luer, Slide clamp, Stabilization component, Spin-lock connector (patient connector/male luer adapter). May be comprised of various generic components: Stopcocks, Clamps (e.g. roller clamp, on-off clamp), Injection sites, Connectors, Manifolds, Filter (0.2um, 1.2um, 5.0um), Check valve, Needleless connector.	PVC tube, Luer lock connector, Check valve, Anti-siphon valve, Filters (0.2um, 1.2um, 5.0um), Clamp (slide or pinch), Flow regulator, Needle free injection port, Protective cap.	Different Difference does not raise new or different questions of safety or effectiveness. See Justification 4
Summary of Non-clinical Tests	• Stabilization component performance • Visual • Catheter Angle • Flow Rate – No Catheter • Flow-rate – With Catheter • Tape Removal • Occlusion • Negative Pressure • Positive Pressure • Clamp and Positive Pressure • Tensile Strength • Power Injection • Mechanical Hemolysis – Aspiration and injection	• Appearance • Dimension • Particulate Contamination • Leakage • Tensile Strength • Flow Rate • Luer Connector (Size, Fluid leakage, Sub-atmospheric pressure air leakage, Stress cracking, Resistance to separation from axial load, Resistance to separation from unscrewing, Resistance to overriding) • Check Valve (Counter flow pressure resistance, Flow rate,	Different Difference does not raise new or different questions of safety or effectiveness. See Justification 5

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Description	Extension Sets (Predicate device)	Extension Set (Subject device)	Comparison to predicate device
	• Luer Connection • Gauging • Liquid and Air leakage • Separation Force • Stress Cracking • Collar Retention • Joint Qualification • Particulate Contamination	Blocking performance, Opening pressure) • Anti-siphon Valve (Counter flow pressure resistance, Flow rate, Blocking performance, Opening pressure) • Liquid Medicine Filter • Needle Free Injection Port (Flow rate, Test for exposure to IPA, Resistance to separation from axial load, Resistance to separation from unscrewing, Resistance to overriding, Backpressure (un-activated), Positive pressure fluid leakage (activated), Sub-atmospheric pressure air leakage (un-activated), Sub-atmospheric pressure air leakage (activated), Duration of activation, Number of activation) • Storage Volume • Clamp (Construction) and Flow Regulator (Construction, Flow rate) • Protective Cap • Chemical performance • Biological performance	
Materials	PVC, LDPE, HDPE, PC, PP, ABS, Methylene Chloride (MC), Tetrahydrofuran (THF)	PVC (TOTM), PC, Silicone, PES, PTFE, MABS, PP, POM, ABS, HDPE, Styrene-Butadiene Copolymer (SBC).	Different Difference does not raise new or different questions of safety or effectiveness. See Justification 6
Biocompatibility	ISO 10993	ISO 10993	Identical
Sterilization	Ethylene Oxide, SAL 10^{-6}	Ethylene Oxide, SAL 10^{-6}	Identical
Sterile	Yes	Yes	Identical

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Description	Extension Sets (Predicate device)	Extension Set (Subject device)	Comparison to predicate device
Single Use	Yes	Yes	Identical

Justification 1: Indications for Use

The subject device, Extension Set, is intended to be used with a vascular access device for direct injection, intermittent infusion, continuous infusion or aspiration. The predicate device was described to be added to an intravascular catheter hub as a conduit for flow to and from the catheter as per K153293, and the subject device is same to it. Extension Sets may be used with pressure injection to a maximum pressure of 200kPa, and the differences do not raise new or different questions of safety or effectiveness according to **Justification 2**. The subject device does not contain a stabilization component which aims to fix the set, and the component has no influence to achieve the intended use. The patient population of the subject device is adults and pediatrics, the difference does not raise new or different questions of safety or effectiveness according to **Justification 3**. Based on the Justification 2 and 3, the differences in the "Indications for Use" of the subject device do not result in a new intended use. So the differences do not raise new or different questions of safety or effectiveness.

Justification 2: Mode of Fluid Delivery

The subject device is intended for gravity use or pressure injection. The gravity use is same to the predicate device. For pressure injection, the subject device is intended for pressure injection to a maximum pressure of 200kPa, while the predicate device for power injection to a maximum pressure of 400 psi. To achieve the maximum pressure of 200kPa, the subject device needs to connect with pressure infusion equipment. The pressure resistance testing of leakage is verified according to ISO 8536-9: 2015 *Infusion equipment for medical use - Part 9: Fluid lines for single use with pressure infusion equipment* and the connection part of the subject device is standard components meeting the requirements of ISO 80369-7: 2021 *Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications*. So the pressure injection of 200kPa is acceptable to achieve the intended use. The difference does not raise new or different questions of safety or effectiveness.

Justification 3: Patient Population

The patient population of the subject device is "adults and pediatrics", while the patient population of the predicate device is "any patients". The subject device has demonstrated to perform to specification and is biocompatible, independent of the patient population. The difference does not raise new or different questions of safety or effectiveness.

Justification 4: Device Components

The subject device and predicate device have the similar components, such as PVC tube, luer lock connector, slide clamp, check valve, filters, pinch clamp and needle free injection port. The pinch clamp of the subject device is similar to the on-off clamp of the predicate device. The subject device has the components of anti-siphon valve and protective cap, which are different from the predicate device. The anti-siphon valve is the same as the check-valve structure except the difference of opening pressure, and meets the performance requirements after testing according to ISO 8536-12:2021 *Infusion equipment for medical use - Part 12: Check valves for single use*. The protective cap is designed to protect the connectors and is secure and easily removable after testing. The differences of configurations between the subject device and predicate device do not raise different questions of safety and effectiveness. Both achieve the same intended use.

Justification 5: Summary of Non-Clinical Tests

The subject device has the components of PVC tube, luer lock connector, check valve, anti-siphon valve, filters (0.2um, 1.2um, 5.0um), clamp (slide or roller), flow regulator, needle free injection port, protective cap, no stabilization component. The different components compared with the predicate device include anti-siphon valve and protective cap. For all components, the verification testing was performed on the subject device and met the requirements of applicable parts of ISO 8536 series, ISO 80369-7: 2021 *Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications* and FDA guidance. For example, the luer lock connector met the requirements of ISO 80369-7, check valve and anti-siphon valve met the requirements of ISO 8536-12: 2021 *Infusion equipment for medical use - Part 12: Check valves for single use*, filters met the requirements of ASTM F838-20 *Standard Test Method for Determining Bacterial Retention of Membrane Filters Utilized for Liquid Filtration* or ISO 8536-4: 2019 *Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed*, clamp and flow regulator met the requirements of ISO 8536-14: 2016 *Infusion equipment for medical use - Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact*, and needle free injection met the requirements of ISO 80369-7: 2021 *Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications*, ANSI/AAMI CN27:2021 *General requirements for Luer activated valves (LAVs) incorporated into medical devices for intravascular applications*, and FDA guidance. In addition, chemical and biological performances, including Reducing matter, metal ions, titration acidity or alkalinity, residue on evaporation, UV absorption, EO residual, ECH residual, sterility and endotoxin were tested as well. Verification results confirm that the differences in the components do not raise new questions of safety and effectiveness.

Justification 6: Materials

The liquid pathway of the subject device is PVC (TOTM) which is a DEHP-free PVC and similar to the material of the predicated device. And they have same PC, ABS, HDPE, PP materials. The materials used by the subject device are common medical materials with no significant clinical safety problems reported. In addition, a biological evaluation was conducted on the subject device according to ISO 10993-1: 2018 *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*, including cytotoxicity, skin sensitization, intracutaneous reactivity, pyrogenicity, acute systemic toxicity, subacute toxicity and hemolysis. It has been demonstrated that the materials used for the device is biocompatible. Based on bench testing of Extension Set, the performance of the subject device meets the requirement of ISO 8536 series, ISO 80369-7, etc. The materials differences have no influence to the product performance. So the differences of materials do not raise new or different questions of safety or effectiveness.

VII. Performance Data

The subject device, Extension Set, was subjected to the following applicable testing to ensure reliable design and performance under the specified testing parameters:

Biocompatibility Testing:

Per ISO 10993-1: 2018 *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process* and FDA guidance, the following tests were performed to ensure the biocompatibility of the subject device.

- In vitro cytotoxicity, per ISO 10993-5: 2009 *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity*
- Skin sensitization, per ISO 10993-10: 2021 *Biological evaluation of medical devices - Part 10: Tests for skin sensitization*
- Intracutaneous reactivity, per ISO 10993-23: 2021 *Biological evaluation of medical devices - Part 23: Tests for irritation*
- Pyrogenicity, per ISO 10993-11: 2017 *Biological evaluation of medical devices - Part 11: Tests for systemic toxicity* and USP <151> *Pyrogenicity Test*
- Acute systemic toxicity, per ISO 10993-11: 2017 *Biological evaluation of medical devices - Part 11: Tests for systemic toxicity*
- Subacute toxicity, per ISO 10993-11: 2017 *Biological evaluation of medical devices - Part 11: Tests for systemic toxicity*
- Hemolysis, per ISO 10993-4: 2017 *Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood* and ASTM F756-17 *Standard Practice for Assessment of Hemolytic Properties of Materials*

Bench Testing:

Per ISO 8536-4: 2019 *Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed*, ISO 80369-7: 2021 *Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications*, FDA guidance "*Intravascular Administration Sets Premarket Submission Notifications (FDA; July 11, 2008)*", etc., the following tests were performed to ensure performance/functionality of the subject device.

- Appearance, per ISO 8536 series.
- Dimensions, per FDA guidance, similar devices and product characteristics.
- Particulate contamination, per ISO 8536 series and USP <788> *Particulate Matter in Injections*
- Leakage, per ISO 8536 series and FDA guidance.
- Tensile strength, per ISO 8536 series and FDA guidance.
- Flow rate, per FDA guidance.
- Luer connector: Size, Fluid leakage, Sub-atmospheric pressure air leakage, Stress cracking, Resistance to separation from axial load, Resistance to separation from unscrewing, Resistance to overriding, per ISO 80369-7: 2021 and FDA guidance.
- Check valve: Counter flow pressure resistance, Flow rate, Blocking performance, Opening pressure, per ISO 8536-12: 2021 *Infusion equipment for medical use - Part 12: Check valves for single use*
- Anti-siphon valve: Counter flow pressure resistance, Flow rate, Blocking performance, Opening pressure, per ISO 8536-12: 2021.
- Liquid medicine filter 0.2um: Bacterial interception test, per ASTM F838-20 *Standard Test Method for Determining Bacterial Retention of Membrane Filters Utilized for Liquid Filtration*
- Liquid medicine filter 1.2um: Retention of latex particles, per ISO 8536-4: 2019 and Candida albicans interception.
- Liquid medicine filter 5.0um: Retention of latex particles, per ISO 8536-4: 2019.
- Needle free injection port: Flow rate, Test for expose to IPA, Resistance to separation from axial load, Resistance to separation from unscrewing, Resistance to overriding, Backpressure (unactivated), Positive pressure fluid leakage (activated), Sub-atmospheric pressure air leakage (unactivated), Sub-atmospheric pressure air leakage (activated), Duration of activation, Number of activation, per ANSI/AAMI CN27:2021 and ISO 80369-7: 2021.
- Storage volume, per ISO 8536-8: 2015 and FDA guidance.
- Clamp, per ISO 8536-14: 2016 *Infusion equipment for medical use - Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact*
- Flow regulator, per ISO 8536-14: 2016.

- Protective cap, per ISO 8536-4: 2019.
- Chemical performance, per ISO 8536-4: 2019.
- Sterility, per ISO 11135: 2014 *Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices*
- Bacterial endotoxin, per ANSI/AAMI ST72: 2019 *Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing*
- ISTA 3A: 2018, *Packaged-Products for Parcel Delivery System Shipment*
- Package performance, per ISO 11607-1: 2019 *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems* and ISO 11607-2: 2019 *Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes*
- Shelf Life Validation, per ASTM F1980-21 *Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices*

Clinical Tests:

Clinical tests were not required to demonstrate performance of Extension Set. Product functionality has been adequately assessed by non-clinical tests.

Animal Tests:

Animal tests were not required to demonstrate performance of Extension Set. Product functionality has been adequately assessed by non-animal tests.

VIII. Conclusions

The results of these tests confirm that the Extension Set meets the design input requirements based on the intended use and support the conclusion that this device is as safe and effective as the legally marketed predicate device Extension Sets (K153293, B.Braun Medical Inc.) and therefore, substantially equivalent.