DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 28, 2014

ICON ORTHOPEDIC CONCEPTS, LLC DBA EDGE ORTHOPAEDICS
Ms. Jan Triani
Director of Quality Assurance and Regulatory Affairs
6 Mars Court, Unit 6-3
Boonton, New Jersey 07005

Re: K142135
Trade/Device Name: REDUCE® Fracture Plating System Line Extension
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: August 1, 2014
Received: August 4, 2014

Dear Ms. Triani:

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" (21CFR 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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K142135

Device Name: REDUCE® Fracture Plating Line Extension

Indications for Use:

EDGE Orthopaedics' REDUCE® Fracture Plating System is intended for use in stabilization and fixation of fresh fractures, revision procedures, joint fusion, and reconstruction of small bones of the hand, feet, wrist, ankles, fingers and toes. The plates are available for use with EDGE Orthopaedics locking and non-locking bone screws.

Plates and screws are intended for single use only. Screws are not intended for use in the spine.

Prescription Use ____X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

5. 510(k) Summary

Date Prepared [21 CFR 807.92(a)(1)]

August 26, 2014

Submitter's Information [21 CFR 807.92(a)(1)]

Jan Triani, Directory of Quality Assurance and Regulatory Affairs
6 Mars Court, Unit 6-3
Boonton, NJ 07005
Phone: (201)543-9388
Fax: (973)794-6813

Establishment Registration Number: 3010726797

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Trade Name:	EDGE Orthopaedics REDUCE® Fracture Plating System
Common Name:	Plate
Classification Name:	Class II, 21 CFR 888.3030, Product Code: HRS
Panel Code:	Orthopedics

Predicate Device [21 CFR 807.92(a)(3)]
EDGE Orthopaedics' VIEW and REDUCE Plating Systems – K140876

Description of the Device [21 CFR 807.92(a)(4)]

The EDGE Orthopaedics' REDUCE® Fracture Plating System Line Extension has been designed to support multiple indications within the forefoot and mid-foot. The line extension includes titanium alloy, sterile packaged H and Box Plates along with sterile titanium alloy bone screws.

The REDUCE Fracture Plating System is offered in a variety of sizes for use with the non-locking and locking bone screws. The screws are available in variety of diameters and lengths to help support the fixation, correction or stabilization of bones.

The corresponding instrumentation (depth gauges, screwdrivers, reamers, and plate benders) to facilitate insertion is found in EDGE's RIVAL Instrument Tray.

The only modifications that were made are the two additional fracture plates: H-plate and Box plate. The manufacturing, packaging and sterilization process are the same as the predicate device.

Intended Use [21 CFR 807.92(a)(5)]

EDGE Orthopaedics' REDUCE® Fracture Plating System is intended for use in stabilization and fixation of fresh fractures, revision procedures, joint fusion, and reconstruction of small bones of the hand, feet, wrist, ankles, fingers and toes. The plates are available for use with EDGE Orthopaedics' locking and non-locking bone screws.

Plates and screws are intended for single use only. Screws are not intended for use in the spine.

This is the same intended use as previously cleared for the REDUCE Plating Systems (K140876). The indication for use statement can be found in Section 4.

Technological Characteristics [21 CFR 807.92(a)(6)]
The subject device is the same device with respect to design, material and indications to the predicate device. There are no technological differences to the subject device.

Performance Data [21 CFR 807.92(b)(1)]
The safety and effectiveness of the line extension is adequately supported by the substantial equivalence information as well as CAD and mathematical analysis included in this submission to conclude the line extension did not create a new worst case.

Clinical Data [21 CFR 807.92(b)(2)]
Clinical data was not used to determine substantial equivalence.

Conclusion [21 CFR 807.92(b)(3)]
The analysis of the line extension for the REDUCE Fracture Plating System in this Premarket Notification supports the conclusion that the subject devices are substantially equivalent to the predicate device.