December 9, 2019

Nebula Surgical Private Limited
Rajat Kumar Khant
Director
Nebula, Narmada Park-3,Amin Marg, Vidyakunj Soc.Main Road
Opp.Kings Heigt
Rajkot, 360005 In

Re: K191793
Trade/Device Name: Nebula Brand Locking Bone Plates and Screws Osteosynthesis Plating System, Nebula Brand of DHS Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: September 10, 2019
Received: September 10, 2019

Dear Rajat Khant:

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. 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 located 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.

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

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 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,

Shumaya Ali, MPH
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191793

Device Name

Nebula Brand Locking Bone Plates and Screws Osteosynthesis Plating System, Nebula Brand of DHS Plating System

Indications for Use *(Describe)*

NEBULA BRAND Locking Bone Plates and Screws Osteosynthesis Plating System, NEBULA BRAND of DHS Plating System are provided non-sterile.
NEBULA BRAND Locking Bone Plates and Screws Osteosynthesis Plating System, NEBULA BRAND of DHS Plating System are indicated for treating fractures of various bones including the clavicle, pelvis, scapula, long bone (humerus, ulna, radius, femur, tibia and fibula), and small bone (metacarpals, metatarsals, phalanges).
The system is indicated for use in adult patients only. All implants are for single use only.

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

This Premarket Notification 510(k) Summary is prepared as required by Section 807.92

Submitter Information

510(k) Submitter:	NEBULA SURGICAL PVT. LTD.
Date Prepared:	06-06-2019
Head Office Address:	"Nebula", Narmada Park-3, Vidyakunj Society Main Road, Opp. Kings Height Appt., Amin Marg, Rajkot - 360005, Gujarat (INDIA)
Factory address :	G/1921/3, Gate no. 02, G.I.D.C. - Metoda, Dist. Rajkot - 360021, Gujarat (INDIA)
Contact:	Rajat Kumar Khant Director (Sales and Marketing) Email: executiveshrikant@gmail.com Phone: +91-9825132632

Submission Information

Proprietary Name:	NEBULA BRAND Locking Bone Plates and Screws Osteosynthesis Plating System, NEBULA BRAND of DHS Plating System
Common or Usual Name:	Orthopaedic Bone Plates and Screws
Classification Name:	21 CFR 888.3030: Plates Fixation, Bone 21 CFR 888.3040: Screws, Fixation, Bone
Product Code:	HRS, HWC
Device Class:	Class II
Classification Panel:	Orthopaedic

Predicate Devices (with corresponding subject Device)

The subject NEBULA BRAND Locking Bone Plates and Screws Osteosynthesis Plating System, NEBULA BRAND of DHS Plating System is submitted as a bundled submission. The following table lists predicate device 510(k) numbers used to demonstrate substantial equivalence. The following subject devices have been aligned with their respective predicate devices:

S No	Subject Device	Predicate Device
Small Fragment		
01	Distal Radius Volar Locking Plate, Left & Right	Synthes (USA) VOLAR DISTAL RADIUS PLATE(K953644)
02	Small Locking Plate	Synthes (USA) 3.5 mm and 4.5 mm Locking Compression Plate(K082807)
03	Distal Tibial Medial Locking Plate, Left & Right	Synthes (USA) Medial Distal Tibia Plate (K001945)
04	Reconstruction Locking Plate 3.5mm	Synthes 4.5 mm LCP Straight Reconstruction Plate (K051986)
05	Clavicle Medial Locking Plate, Left & Right	Synthes 3.5mm LCP Clavicle Plate System (K111540)

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06	Distal Humerus D/L @ Support LCP, Left & Right	Synthes 3.5 MM LCPDISTAL HUMERUS SYSTEM (K033995)
07	Distal Humerus Medial LCP Plate, Left & Right	Synthes 3.5 MM LCP DISTAL HUMERUS SYSTEM (K033995)
08	Distal Fibula VA LCP, Left and Right	Synthes 2.7mm / 3.5mm LCP Distal Fibula Plate (K073460)
09	Anterolateral Distal Tibia Locking Plate, Left & Right	Synthes (USA) 2.7mm / 3.5mm LCP Anterolateral Distal Tibia Plate (K092812)
10	Medial Proximal Tibia Locking Plate, Left & Right	Synthes (USA) 3.5 / 4.5mm LCP® Medial Proximal Tibia Plate (K032269)
11	Posterior Medial Proximal Tibial Locking Plate	Synthes 3.5mm LCP Proximal Tibia Plates(K030597)
12	Anatomical Proximal Tibia Locking Plate, Left and Right	SYNTHES ANATOMICAL LOCKING PLATE SYSTEM (K961413)
	Large Fragment	
13	Narrow and Broad Locking Plates Ø 4.5mm	Synthes 3.5 and 4.5mm Locking Compression Plate System (K082807)
14	Broad Locking Plate Ø 4.5mm	Synthes 3.5 and 4.5mm Locking Compression Plate System (K082807)
15	Distal Femur Locking Plate, Right & Left	Synthes LCP Distal FemurPlates (K062564)
16	Lateral Tibia Locking Plate, Right & Left	Synthes LCP Proximal Tibia Plate (K011978)
17	Philos Locking Plate	Synthes (USA) LCP® Proximal Humerus Plates, Long (K041860)
18	Narrow LC DCP Plate, 3.5mm	Synthes 3.5 and 4.5mm Locking Compression Plate System (K082807)
19	D.H.S. Plate 135 Degree with Dynamic Hip Screw (Non- Locking) Long Barrel and Short Barrel D.H.S. Plate 130 Degree with Dynamic Hip Screw (Non- Locking) Long Barrel and Short Barrel	Synthes Limited Contact- Dynamic Hip Screw Implant (LC-DHS) for K923613S Synthes Titanium Limited Contact-Dynamic Hip Screw Implant (Ti LC- DHS) for K953607
	Locking and Non-Locking Screw	
20	D.H.S. Lag Screw	Synthes Limited Contact- Dynamic Hip Screw Implant (LC-DHS)" for K923613Synthes Titanium Limited Contact-Dynamic Hip Screw Implant (Ti LC-DHS) for K953607
21	Locking Screw, Ø 2.7mm - Self Tapping	Synthes Small Fragment Dynamic CompressionLocking (DCL) System (K000684)
22	Locking Screw, Ø 3.5mm - Self Tapping	Synthes Small Fragment Dynamic Compression Locking (DCL) System (K000684)
23	Cortical Screw Ø 3.5mm 20 TPI (Self Tapping)	Synthes Cortical Screws K112583
24	Cannulated Cancellous Screw Ø 4.0 mm, 16mm Thread, 32mm Thread and Full Thread	Synthes (USA) 6.5 mm Cancellous Screws (K061621)
25	Cortical Screw Ø 4.5mm, Self-Tapping	Synthes Cortical Screws K112583
26	Locking Screw, Ø4.9 mm Self-Tapping	Synthes Large Fragment Dynamic Compression Locking (DCL) System (K000682)
27	Cancellous Screw, Ø6.5mm, 16mm Thread, 32mm Thread and Full Thread	Synthes (USA) 6.5 mm Cancellous Screws (K061621)

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Device Description

The NEBULA BRAND Locking Bone Plates and Screws Osteosynthesis Plating System, NEBULA BRAND of DHS Plating System is submitted as a bundled submission. Throughout the submission there is a mention of NEBULA BRAND Locking Bone Plates and Screws Osteosynthesis Plating System, NEBULA BRAND of DHS Plating System that represents the range of products covered under this 510(k) submission. The NEBULA BRAND Locking Bone Plates and Screws Osteosynthesis Plating System, NEBULA BRAND of DHS Plating System are subdivided into the following categories:

S. No.	Category	Types
01	Mini, Small and Large	Volar Plates, T-Shaped, Angled Plates, Reconstruction plates
02	Dynamic compression	Small, Narrow, Lengthening
03	Hip Plate	Dynamic Hip Screw Plates
04	Bone Screws	Locking and Non-Locking Version

Generally, there are the following types of bone plates used with cortical (cortex), cancellous, and Locking Screws. These bone plates are generally designed on the basis of the bone contour and anatomy.

S. No.	Type	Subtype
01	Mini, Small and Large Fragment	Volar Plates, T-Shaped, Angled Plates, Reconstruction plates
02	Dynamic compression	Small, Narrow, Lengthening Narrow, Broad Plates
03	Hip Plate	Dynamic Hip Screw Plates

NEBULA BRAND Locking Bone Plates and Screws Osteosynthesis Plating System, NEBULA BRAND of DHS Plating System consists of various shape and sizes of plates featuring compression and locking holes, full-threaded-cortical, locking self-tapping screws, compression and dynamic screws.

The plates and screws are fabricated from Stainless Steel and Titanium. The implants are supplied non-sterile and should be steam-sterilized prior to use.

The system contains several models based on the size of the device and application site such as fixation/reconstruction of small fragment bones, forefoot, mid-foot, rear-foot, and the ankle. The plate implants are available in models such as Reconstruction Plates, T- Plates, , Anatomical Plates, and Clavicle Plates.

These all are mainly divided into the following:

- Large Fragment Plates
- Small Fragment Plates
- Hip Plates (DHS Plate)

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The thickness of the plates varies from 1.3mm to 6mm; and the number of the holes varies from 2 to 20. The Locking screw implants are in corresponding diameter ranges from 2.7mm, 3.5mm, and 4.9 mm diameters with lengths varying as per the requirements and lengths of 10mm to 90 mm

The Non-locking cortical screw implants are in 3.5mm and 4.5mm diameter and length range from 10mm to 80mm.

The Non-locking cancellous screws are in 6.5mm diameter and length range from 30mm to 120mm The Non-locking cannulated cancellous screws are in 4.0mm diameter and length range from 10mm to 72mm

The Lag Screw is of 12.5mm Diameter and length from 50mm to 120mm

Indications for Use

NEBULA BRAND Locking Bone Plates and Screws Osteosynthesis Plating System, NEBULA BRAND of DHS Plating System are provided non-sterile.

NEBULA BRAND Locking Bone Plates and Screws Osteosynthesis Plating System, NEBULA BRAND of DHS Plating System are indicated for treating fractures of various bones including the clavicle, pelvis, scapula, long bone (humerus, ulna, radius, femur, tibia and fibula), and small bone (metacarpals, metatarsals, phalanges).

The system is indicated for use in adult patients only. All implants are for single use only.

Comparison of Technological Characteristics

A comparison between the NEBULA BRAND Locking Bone Plates and Screws Osteosynthesis Plating System, NEBULA BRAND of DHS Plating System and predicate devices has been performed which has resulted in demonstration of similarities in dimensional and performance criteria. The subject and predicate devices are similar in geometry and dimensions, intended and indicated uses, materials, sterilization methods, and performance.

Non-Clinical Performance Testing

NEBULA BRAND Locking Bone Plates and Screws Osteosynthesis Plating System, NEBULA BRAND of DHS Plating System are of similar design and pattern as well as similar intended use. Clinical information was not necessary to demonstrate substantial equivalence. Performance of the NEBULA BRAND Locking Bone Plates and Screws Osteosynthesis Plating System, NEBULA BRAND of DHS Plating System has been demonstrated through the test parameters outlined in ASTM F-382 and ASTM F-384 to conduct Static and Dynamic Four Point Bend Testing. Torsional and Axial pullout testing was conducted on the screws per ASTM F-543.

Conclusion

From the data presented, the NEBULA BRAND Locking Bone Plates and Screws Osteosynthesis Plating System, NEBULA BRAND of DHS Plating System are substantially equivalent in performance for the indications and predicate devices identified.