Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION
Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City

CERTIFICATE OF MEDICAL DEVICE REGISTRATION

Pursuant to provisions of Republic Act No. 3720 as amended, known as the Foods, Drugs, Devices and Cosmetics Act and Republic Act 9711, known as the Food and Drug Administration (FDA) Act of 2009 and its implementing Rules and Regulations (IRR), the product described hereunder has been found to conform with the requirements and standards for registration of medical device products per existing regulations in force as of date hereof.

CMDR Number	:	CMDR-2024-02993
Particulars of the Product		
Brand Name	:	ClaroNav Kolahi
Product Name	:	Navient Image Guided Navigation System
Code(s) / Size(s)	:	955-NE-NE
Contents	:	N/A
Classification	:	B
Intended use	:	Intended to be used as an aid for precisely locating anatomical structures in either open or percutaneous procedures.
Shelf-Life	:	service life of 5 years
Storage Condition	:	Storage temperature -25°C to 45°C, RH 10% to 90%, ATM Pressure 700 - 1060 hPa
Primary Packaging for Commercial Presentation	:	packed in double wall cardboard and protective foam around the box
Particulars of the Manufacturer		
Name and Address of the Manufacturer	:	ClaroNavKolahi Inc. - 1140 Sheppard Avenue West, Unit 10 Toronto, Ontario, Canada, M3k 2A2
Particulars of the Trader (if applicable)		
Name and Address of the Trader	:	
Particulars of the Importer/Distributor Company Responsible for Placing the Product in the Market		
Name and Address of the Importer	:	Dubbel Medical Corporation - Unit 202, 2nd Floor, Ablaza Building, #117 E Rodriguez Sr. Avenue, Quezon City
Name and Address of the Distributor	:	Dubbel Medical Corporation - Unit 202, 2nd Floor, Ablaza Building, #117 E Rodriguez Sr. Avenue, Quezon City

This marketing authorization shall be valid until 11 June 2029 subject to the conditions listed on the reverse side. No change in information, labelling and commercial presentation of this product shall be made at any time during the effectivity of this registration without prior written approval of this Office.

This authorization is subject to suspension, cancellation, or recall should any violation of FDA laws, and its implementing rules and regulations, involving the product be committed.

Witness My Hand and Seal of this Office, this 11th day of June, 2024

BY AUTHORITY OF THE DIRECTOR GENERAL

DR. VALERIANO V. TIMBANG, JR.
OFFICER-IN-CHARGE, DIRECTOR IV

INITIAL
DTN : 20231101130846
O.R. No. : SEQ#110623670426
Amount : P7,575.00
Date Issued : 06 November 2023
/AJC

FDA-0487782

MANDATORY REQUIREMENT:

1. This product must be available only in drugstores, hospitals and other legal outlets.
2. The labelling of each device must state:
   a) The date (month/year) within which to use said device, whenever applicable.
   b) The lot or batch number, whenever applicable.
   c) Product registration number
   d) Name and address of local distributor/importer.

SPECIAL CONDITION:

Provided that nothing in the registration of the product herein granted shall be interpreted or construed as an endorsement or representation by FDA, that Registrant has the right privilege to the use of the name or brand so registered; Registrant hereby agree and affirm to indemnify and/or hold FDA free and harmless against any and all third-party claims on infringement of patent, trademark or industrial design rights arising from the registration of the product(s) listed on the other side hereof.