An official website of the United States government Here's how you know

NIH Websites Are Changing

- Get the Latest Updates and FAQs on the transition
- Per Executive Order 14434, federal agencies are now using "Super Intelligence" (SI) in place of "Artificial Intelligence" (AI). You may see both terms across NIH content during this transition.

ACCESS GUDID
IDENTIFY YOUR MEDICAL DEVICE

DEVICE: SprintRay Nightguard Firm 2 – Midnight Purple –1 Kg (00850039704642)

Notice: Any discrepancies with this record compared to the label? If so, send a picture of the label to GUDIDSupport@fda.hhs.gov.

DEVICE IDENTIFIER (DI) INFORMATION

Brand Name: SprintRay Nightguard Firm 2 - Midnight Purple -1 Kg
Primary DI Number: 00850039704642
Version or Model: SRI-0202147
Issuing Agency: GS1
Commercial Distribution Status: In Commercial Distribution
Commercial Distribution End Date:
Catalog Number:
Device Count: 1
Company Name: Sprintray, Inc.
Labeler D-U-N-S® Number*: 063005260 *Terms of Use
Device Description: SprintRay NightGuard Firm 2 is indicated for the fabrication of dental appliances such as mouthguards and nightguards.

DEVICE CHARACTERISTICS

What MRI safety information does the labeling contain?	Labeling does not contain MRI Safety Information
Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437):	No
Device labeled as "Not made with natural rubber latex":	No
For Single-Use:	No
Prescription Use (Rx):	Yes
Over the Counter (OTC):	No
Kit:	No
Combination Product:	No
Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P):	No

GMDN

GMDN© Term Code, Names and Definitions (*Terms of Use): **GMDN®** is a registered trademark of The GMDN Agency. All rights reserved. Used under licence from The GMDN Agency Ltd.

GMDN Term Code	GMDN Term Name	GMDN Term Definition	GMDN Term Status	Implantable ?
16730	Dental appliance fabrication material, resin	A resin intended to be used in the dental laboratory to manufacture a patient-worn dental prosthesis or appliance (e.g., denture base, occlusal splint/night guard), that either: 1) polymerizes under heat (heat-cured), light (light-cured), and/or after a period of time (self-cured); or 2) can be shaped by a dental mill [e.g., based on computer-aided design/computer-aided manufacturing (CAD/CAM) technology]. It may in addition be intended to fabricate non-patient-worn devices (e.g., drilling templates using 3-D printing). After application, this material cannot be refabricated.	Active	false

FDA PRODUCT CODE

Product Code	Product Code Name
KMY	Positioner, Tooth, Preformed

FDA PREMARKET SUBMISSION

FDA Premarket Submission Number	Supplement Number
Premarket Submission Number Not Available/Not Released	

Device Exempt from Premarket Submission: Yes

STERILIZATION

Device Packaged as Sterile: No
Requires Sterilization Prior to Use: No

Sterilization Method
No Sterilization Methods Found

STORAGE AND HANDLING

Storage and Handling
Special Storage Condition, Specify: Store NightGuard Firm 2 at 15-25oC (60-77oF) and avoid direct sunlight
Special Storage Condition, Specify: Keep the bottle closed and/or the tank lid securely attached when not in use.
Special Storage Condition, Specify: Before disposal, completely polymerize

CLINICALLY RELEVANT SIZE

Size Type Text
Weight: 1 Kilogram

DEVICE RECORD STATUS

Public Device Record Key: 0f73f3f5-be08-41dc-b65f-e6ac4193274c
Public Version Date: April 01, 2024
Public Version Number: 1
DI Record Publish Date: March 22, 2024

ALTERNATIVE AND ADDITIONAL IDENTIFIERS ADDITIONAL IDENTIFIERS

PACKAGE DI

Package DI Number	Quantity per Package	Contains DI Package	Package Discontinue Date	Package Status	Package Type
No Package DIs found					

SECONDARY DI

Issuing Agency	Secondary DI Number
No Secondary DIs found	

UNIT OF USE DI

Unit of Use DI Number: No Unit of Use DI Numbers Found

DIRECT MARKING (DM)

Device Subject to Direct Marking (DM), but Excepted: No
DM DI Different from Primary DI: No
DM DI Number: None

PRODUCTION IDENTIFIER(S) IN UDI

Lot or Batch Number: Yes
Serial Number: No
Expiration Date: Yes
Manufacturing Date: Yes
Donation Identification Number: No

CUSTOMER CONTACT

Phone: 800-914-8004
Email: support@sprintray.com