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Date Prepared	April 15, 2019		
Trade Name	General Cutting Contra Handpiece		
Common Name	Handpiece, Contra-And Right-Angle Attachment, Dental		
Classification Name	Dental Handpiece and Accessories		
Product Code	EGS	Class I	872.4200
Predicate Device	K972569	NAKANISHI INC.	E-Type Speed Increaser Contra Angle, ES-95
Reference Devices	K113655	NAKANISHI, INC.	Ti-Max X Turbine
	K073652	NAKAMURA	ND LOWSPEED AIRMOTOR

Device Description

The *General Cutting Contra Handpiece* features an allowable maximum motor speed at 40,000 min^{-1}. The handpieces are provided optic and non-optic and are designed with a contra-angle appearance. Models are available to be connected directly onto motors compliant to ISO 3964. Available handpieces include the *S-Max M Contra Series*, *Ti-Max X Contra Series*, *Ti-Max Z Contra Series and the Ti-Max nano Series*.

Indications for Use

The *General Cutting Contra Handpiece* is powered by either an air-motor or electronic micromotor for use in general dentistry. The device is intended for cutting and grinding teeth, cavity preparations, tooth and crown preparations, finishing and trimming teeth and filling materials and removal of crowns and filling materials.

Summary of Technological Characteristics

As with the predicate devices referenced above, the *General Cutting Contra Handpiece* is intended for dental treatment. The handpieces are powered by either an air-motor or electronic micro motors compliant to ISO 14457 with couplings compliant to [ISO 3964 (EN ISO 3964)]. Friction Grip Burs and Contra Angle Burs that conform to ISO 1797-1 (EN ISO 1797) are to be used with the *General Cutting Contra Handpiece*. The allowable maximum motor speed rotation for the handpieces is at 40,000 min^{-1}. The handpieces are available

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with fiber optic and non-optic. All models include a water spray feature. The *General Cutting Contra Handpiece* is provided non-sterile, so it must be sterilized prior to first use and sterilized after each subsequent use using steam sterilization (moist heat sterilization).

The proposed device shares technological characteristics with the predicate device. The proposed device also has some differences in technological characteristics from those of the predicate device. Any differences in the technological characteristics are minor and reflect market strategy and/or perceived user preferences.

	Proposed Device: NAKANISHI INC. [K182999]	**Predicate Device: NAKANISHI INC. [K972569]**	**Reference Device: NAKANISHI INC. [K113655]**	**Reference Device: NAKAMURA DENTAL [K073652]**
Trade Name	*General Cutting Contra Handpiece*	E-Type Speed Increaser Contra Angle, ES-95	Ti-Max X Turbine Series	ND E-TYPE CONTRAANGLE
Model Numbers	S-Max M: M15L, M15, M25L, M25, M95L, M95 Ti-Max X: X10L, X10, X12L, X12, X15L, X15, X20L, X20, X25L, X25, X85, X85L, X95, X95L Ti-Max Z: Z10L, Z15L, Z25L, Z85L, Z95L Ti-Max nano: nano15LS, nano25LS, nano95LS	ES-95	Miniature Head: X500; X500L; X500K; X500KL; X500SL; X500WL; X500BL Standard Head: X600; X600L; X600K; X600KL; X650L; X650KL; X600SL; X600WL; X600BL; X600WLED; X600BLED Torque Head: X700; X700L; X700K ; X700KL; X700SL; X700WL; X700BL;	EC-20L EC-30BL EG-20L EGG-20L
Indication for Use	The General Cutting Contra Handpiece is powered by either an air-motor or electronic micromotor for use in general dentistry. The device is intended for cutting and grinding teeth, cavity preparations, tooth and crown preparations, finishing and trimming teeth and filling materials and removal of crowns and filling materials.	The device is intended for use where high speed such as 200,000 rpm is required in general dentistry with or without use of coolant; such as cutting a tooth for cavity and/or crown preparation and finishing, cutting and/or finishing of dentures, denture bases, crowns, inlays and metal plates. The device is driven by an electrical micrometer or an air motor handpiece that has the ISO-3964 coupling.	The Ti-Max X Series is an air-powered dental handpiece intended for removing carious material, reducing hard tooth structure, cavity preparation, finishing tooth preparations and restorations and polishing teeth.	ND e-type contra p is powered by either low speed air-motor or electric micromotor for removing carious material and excess filling material, cavity and crown preparation, root
Weight	53.5g – 78.5g	62.5 g	36.7 – 52.5g	Unknown

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Coupling Type	ISO 3964 (EN ISO 3964) Standard Coupling	ISO 3964 Standard Coupling	Nakanishi (NSK), KaVo, W&H, Bien Air, Sirona	ISO 3964 Standard Coupling
Burs	ISO 1797-1 (Type1) ISO 1797-1 (Type3)	ISO-1797-1 (Type 3) (1.6mm or .0630in)	ISO 1797-1 Type 3	EC-20L : ISO 1797-1 (Type1) EC-30BL: ISO 1797-1 (Type1) EG-20L : ISO 1797-1 (Type1) EGG-20L:Unknown
Max Rotation Speed (motor)	40,000min^{-1} max	40,000min^{-1} max	Miniature Head: (500): 390,000 – 450,000 Standard Head: (600): 380,000 – 440,000 Torque Head: (700): 300,000 – 360,000	EC-20L :20,000min^{-1} EC-30BL :30,000min^{-1} EG-20L :20,000min^{-1} EGG-20L:Unknown
Gear Ratio Max rotation speed (handpiece)	16:1 Reduction-2,500min^{-1} 10:1 Reduction-4,000min^{-1} 4:1 Reduction-10,000min^{-1} 1:1 Direct Drive-40,000min^{-1} 1:5 Increasing-200,000min^{-}	1:5 Increasing-200,000min^{-1}	N/A	16:1 Reduction: Unknown 4:1 Reduction: 5,000min^{-1} 1:1 Direct Drive: 30,000min^{-1}
Cleaners/ Lubricants	NSK PANA SPRAY Plus (K163483)	Mineral Oil	Care3 Plus automatic handpiece cleaning/lubrication tabletop unit [K081811]	YOSHIDA Lubrication Oil Spray
Sterilization Method	Steam Autoclave (Moist Heat)	Steam Autoclave (Moist Heat)	Steam Autoclave (Moist Heat)	Steam Autoclave (Moist Heat)
Sterilization Standard	ANSI/AAMI/ISO 17665-1:2006	ISO 17665-1	EN ISO 17665-1:2006	Unknown

Summary of Performance Testing

The *General Cutting Contra Handpiece* was developed and is produced under considerations of all applicable technical standards, internal specifications, and FDA guidance documents. The product's conformance with applicable international and internal standards was verified in the course of bench testing. Tests were performed on the handpiece including verification/validation testing to internal functional specifications which demonstrated that the device is substantially equivalent and complies with FDA requirements stated in Guidance Document "Dental Handpieces – Premarket Notification [510(k)] Submissions - Guidance for Industry and FDA Staff". Sterilization has been validated in conformance to the FDA recognized consensus standard AAMI/ANSI/ISO 17665-1:2006; "Sterilization of Health Care Products – Moist

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Heat – Part 1: Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices." Documentation was provided demonstrating that the *General Cutting Contra Handpiece* complies with the FDA requirements stated in Guidance for the "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling - Guidance for Industry and Food and Drug Administration Staff". Biocompatibility evaluations were selected in accordance with AAMI/ANSI/ISO 10993-1: "Biological evaluation of medical devices – Part 1: Evaluation and testing" and FDA Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process- Guidance for Industry and Food and Drug Administration Staff". In addition, testing for electrical safety was performed in accordance with ISO 14457.

Conclusion

NAKANISHI, INC. considers the *General Cutting Contra Handpiece* to be substantially equivalent to the predicate devices listed above. This conclusion is based on the similarities in primary intended use, principles of operation, functional design, and established medical use.

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