

December 11, 2023

Essential Dental Systems Inc.
Jason Guzman
R&D Manager
89 Leuning Street
South Hackensack, New Jersey 07606

Re: K223340

Trade/Device Name: EDS Calculus Softener (TURBO-CR™)

Regulation Number: 21 CFR 872.4850

Regulation Name: Ultrasonic Scaler

Regulatory Class: Class II

Product Code: ELC

Dated: November 14, 2023

Received: November 15, 2023

Dear Jason Guzman:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Michael E. Adjodha -S

Michael Adjodha, MChE, RAC, CQIA
Assistant Director

DHT1B: Division of Dental and
ENT Devices

OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices

Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K 2 2 3 3 4 0

Device Name

EDS Calculus Softener (TURBO-CR™)

Indications for Use (Describe)

Softens dental calculus, tartar, and/or plaque to facilitate easier removal; Reduces scaling time; May be used in hand and ultrasonic scaling procedures.

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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Section 5 - 510(k) Summary

[21 CFR 807.92 (c)]

5.1. Application Information: [807.92 (a)(1)]

Date Prepared: May 11, 2023

Company Name and Essential Dental Systems, inc.

Address: 89 Leuning Street, South Hackensack, NJ 07606

Contact: Mr. Jason Guzman Ms. Shamal Kadam

Designation: R&D Manager **OR** Regulatory Affairs Specialist

Email: jguzman@edsdental.com skadam@edsdental.com

Phone #: 201-487-9090 ext.119 201-487-9090 ext.114

Fax #: 201-487-5120 201-487-5120

List of devices for which clearance is requested: A scaler/periodontal debriding gel called EDS Calculus Softener (TURBO-CR™)

5.2. Name of the Device: [807.92 (a)(2)]

Trade name: EDS Calculus Softener (TURBO-CR™)

Device Type: Scaler/periodontal debriding solution/gel

Regulation Description: A periodontal debriding solution/gel

Review Panel: Dental

Regulation Number: 21 CFR 872.4850 (Scaler)

Device class: Class II

Product Code: ELC

5.3. Predicate Device Information: [807.92 (a)(3)]

The legally marketed devices to which substantial equivalence is being claimed are:

Table 5.1 – Predicate Devices

	Primary predicate device	Reference Predicate device
Device	SofScale – Periodontal debriding solution/gel	Therasol Tartar Dissolver
Manufacturer	Dentsply	OraTec
510K number	K903163	510k Exempt
Regulation Number	21 CFR 872.4850	21 CFR 872.4850
Product Code	ELC	ELC

NOTE: The Predicate device has not been subject to a design-related recall.

5.4. Device Description: [807.92 (a)(4)]

EDS Calculus Softener (TURBO-CR™) is a professional use only product to be used by a dental hygienist to aid in the cleaning and removal of dental plaque, mineralized calculus and/or tartar from subgingival root surfaces and supragingival areas of teeth. The composition helps remove the etiological factors which have been implicated in fostering periodontal disease. The device contains chelating agents and detergents which reduce the hardness of mineralized plaque, calculus, and/or tartar. It consists of two component pastes that are combined in a dual barrel syringe for ease of dispensing and consistent dosage. The device contains an acidic and alkaline paste which effervesces or foams upon mixing through a mixing tip. This effervescence helps drive the activated composition into the “hard to reach” interproximal spaces between teeth as well as into the subgingival regions where tartar/plaque and or dental calculus can accumulate.

It is packaged in the familiar double-barrel syringe configuration used by numerous other dental materials. The double barrel syringe is placed into a manual cartridge gun (commonly available at the dental clinic) and the composition is dispensed into a dental tray which is then placed over the patient’s dental arch for cleaning. The steps required to properly express the calculus softening composition are: remove cap, attach mixer, place into manual cartridge gun, express the material into a dental tray, and then place into the patient’s mouth over the dental arch to be cleaned/debrided for 60 seconds. The patient is then instructed to rinse and the dental scaling can commence by the dental hygienist. After use, the mixer/dispensing tip and dental tray should be discarded and the cap replaced. The device is provided non-sterile and does not contain fluoride or any whitening agents.

5.5. Device Configuration: [807.92 (a)(4)]

The device configuration is:

Table 5.2 – Device Contents

Contents	Amount
Dual chambered syringes each containing 30 or 75 gm periodontal debriding solution/gel	1
Mixer tips	15

5.6. Device Composition:

❖ **Paste/Gel 1:**

- | | |
|---|--|
| <ul style="list-style-type: none"> a. Water b. Glycerol c. Polyethylene Glycol (MW 600) | <ul style="list-style-type: none"> d. Sodium Dodecyl Sulfate e. Xanthan Gum f. Hydrated Silica |
|---|--|

- g.* Sodium Saccharin
- h.* Sodium Dihydrogen Phosphate
- k.* FD&C Blue 1
- i.* Phosphoric Acid
- j.* Sodium Acid Pyrophosphate

❖ **Paste/Gel 2:**

- a.* Water
- b.* Glycerol
- c.* Polyethylene Glycol (MW 600)
- d.* Sodium Dodecyl Sulfate
- e.* Peppermint Oil
- f.* Xanthan Gum
- g.* Hydrated Silica
- h.* Sodium Bicarbonate
- i.* Sodium Saccharine
- j.* Tetrasodium Pyrophosphate
- k.* FD&C Yellow 5

5.7. Intended Use / Indication for Use: [807.92 (a)(5)]

Softens dental calculus, tartar, and/or plaque to facilitate easier removal; Reduces scaling time; May be used in hand and ultrasonic scaling procedures.




5.8. Substantial Equivalence Discussion: [807.92 (a)(6)]

A comparison of **EDS Calculus Softener (TURBO-CR™)** and the predicate devices indicates the following similarities and differences to the devices which received 510(k) clearance:

Table 5.3 - Comparison of Characteristics

	Proposed Device	Primary Predicate Device	Reference Predicate Device
Device Name	EDS Calculus Softener (TURBO-CR™)	SofScale	Therasol Tartar Dissolver
510(k) Number	K223340 (under review)	K903163	510k Exempt
Manufacturer	Essential Dental Systems	Dentsply	OraTec
Indications for Use	Softens dental calculus / tartar / plaque to facilitate easier removal; Reduces scaling time; May be used in hand and ultrasonic scaling procedures	Softens calculus to facilitate easier removal; Reduces scaling time; May be used in hand and ultrasonic scaling procedures	indicated to aid in the removal or debridment of dental calculus, plaque or tartar.

	Proposed Device	Primary Predicate Device	Reference Predicate Device
Composition	<p><u>Paste/Gel 1</u> – Water, Glycerol, Polyethylene Glycol (MW 600), Sodium Dodecyl Sulfate, Xanthan Gum, Hydrated Silica, Sodium Saccharin, Sodium Dihydrogen Phosphate, Phosphoric Acid, Sodium Acid Pyrophosphate, FD&C Blue 1.</p> <p><u>Paste/Gel 2</u> – Water, Glycerol, Polyethylene Glycol (MW 600), Sodium Dodecyl Sulfate, Peppermint Oil, Xanthan Gum, Hydrated Silica, Sodium Bicarbonate, Sodium Saccharine, Tetrasodium Pyrophosphate FD&C Yellow 5.</p>	<p>Paste/Gel Water, Denatured Ethyl Alcohol, Hydroxyethylcellulose, Sodium Ethylenediaminetetraacetic Acid (EDTA), Polysorbate 80, Sodium Lauryl Sulfate, Sodium Bicarbonate, Flavor, Aspartame, FD&C Green #3.</p>	<p>Water, Tetrapotassium Pyrophosphate, Sodium Tripolyphosphate, Sodium Bicarbonate, Citric Acid And Sodium Fluoride.</p>
Color	<p>Paste 1 Yellow, Paste 2 Blue, Green upon mixing.</p>	<p>Green</p>	<p>Colorless</p>
Patient Contacting Material(s)	<p>Gel/Paste 1 – Water, Glycerol, Polyethylene Glycol (MW 600), Sodium Dodecyl Sulfate, Xanthan Gum, Hydrated Silica, Sodium Saccharin, Sodium Dihydrogen Phosphate, Phosphoric Acid, Sodium Acid Pyrophosphate, FD&C Blue 1.</p> <p>Gel/Paste 2 – Water, Glycerol, Polyethylene Glycol (MW</p>	<p>Water, Denatured Ethyl Alcohol, Hydroxyethylcellulose, Sodium Ethylenediaminetetraacetic Acid (EDTA), Polysorbate 80, Sodium Lauryl Sulfate, Sodium Bicarbonate, Flavor, Aspartame, FD&C Green #3.</p>	<p>Water, Tetrapotassium Pyrophosphate, Sodium Tripolyphosphate, Sodium Bicarbonate, Citric Acid And Sodium Fluoride.</p>

	Proposed Device	Primary Predicate Device	Reference Predicate Device
	600), Sodium Dodecyl Sulfate, Peppermint Oil, Xantham Gum, Hydrated Silica, Sodium Bicarbonate, Sodium Saccharine, Tetrasodium Pyrophosphate FD&C Yellow 5.		
Device Description	EDS Calculus Softener (TURBO-CR™) is a professional use only product to be used by a dental hygienist to aid in the cleaning and removal of dental plaque and mineralized calculus or tartar. The device contains chelating agents and detergents which reduce the hardness of or soften mineralized plaque, calculus, and/or tartar.	Dentsply SofScale is a professional use only product to be used by a dental hygienist to aid in the cleaning and removal of dental plaque and mineralized calculus or tartar. The device contains chelating agents and detergents which reduce the hardness of or soften mineralized plaque, calculus, and/or tartar.	Therasol Tartar Dissolver is an over the counter use product that is designed to loosen, soften, or partially dissolve dental calculus, plaque and/or tartar between dental visits. The device contains chelating agents and sodium bicarbonate which reduce the hardness of or soften mineralized plaque, calculus, and/or tartar.
Picture of Device			
Intended Use	Softens calculus, tartar, or plaque to facilitate easier removal; Reduces scaling time; May be used in hand and ultrasonic scaling procedures.	Softens calculus, tartar, or plaque to facilitate easier removal; Reduces scaling time; May be used in hand and ultrasonic scaling procedures.	Softens calculus, tartar, or plaque to facilitate easier removal; Reduces scaling time in between office visits; May be used in hand and ultrasonic scaling procedures.



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Essential Dental Systems, inc.

89 Leuning Street, South Hackensack, NJ 07606

Submission Number: K223340
 EDS Calculus Softener (TURBO-CR™)
 Traditional 510(k) – Original

	Proposed Device	Primary Predicate Device	Reference Predicate Device
Technology Comparison	The dual gel/paste composition contains chelating agents, detergents, mild abrasives, sodium bicarbonate, gelling agents, and flavoring that are mixed upon delivery into a dental tray via a double barrel syringe. Upon mixing of the two pastes, the material forms a penetrating foam that is driven into the “hard to reach” interproximal areas between teeth and subgingivally to aid in the removal of dental calculus, tartar, and/or plaque. The material is allowed to contact the gumline for 1 minute before rinsing and scaling by the dental hygienist.	The single gel/paste composition contains chelating agents, detergents, sodium bicarbonate, gelling agents, flavoring, and an organic solvent (ethyl alcohol) that is delivered via a single barrel syringe directly to the gum line. The material is allowed to contact the gumline for 1 minute before scaling by the dental hygienist.	The composition, a powder containing chelating agents, sodium bicarbonate, and sodium fluoride, is mixed with water before rinsing for 1 minute in order to soften dental calculus, plaque, and/or plaque. Brushing is then performed in order to remove the softened dental calculus, tartar, and/or plaque. This process is performed daily in order to reduce dental calculus, tartar , and/or plaque in between dental visits.
Differences*	The EDS Calculus Softener (TURBO-CR™) is a two component gel/paste composition that effervesces /foams upon mixing which allows for penetration of the material into the hard to reach areas. A color change when the two pastes are combined ensure proper mixing of the two components. This device is for professional use only.	SofScale is a single gel/paste composition delivered in a single barrel syringe. This device is for professional use only. This device does not contain fluoride.	Therasol Tartar Dissolver is a powder composition that is mixed with water before rinsing. This composition is an over the counter device.

The **EDS Calculus Softener (TURBO-CR™)** is substantially equivalent to the primary predicate device, **SofScale (#K903163)** and reference predicate device **Therasol Tartar Dissolver (510k exempt)**. These compositions are intended for use as water-based external communicating devices designed for an equivalent dental application, to aid in calculus/tartar/plaque removal, and have comparable physical properties, performance specifications and share several specific chemical components. The duration of contact for both devices is short term (<24 hrs). The maximum contact duration of the device in question *is 2 minutes at maximum*. The principal composition of the **EDS Calculus Softener (TURBO-CR™)** is substantially equivalent to the commercially available predicate devices, **SofScale (#K903163)** and **TheraSol Tartar dissolver (510k exempt)** in that the main ingredient that facilitates the primary function of these devices is the incorporation of a chelating agent capable of sequestering ions comprising dental calculus, plaque, and or tartar. Each of the aforementioned predicate devices contain specific chemical components that are identical or equivalent to those found in the **EDS Calculus Softener (TURBO-CR™)**. All of the components found in the predicate devices have been used in legally marketed devices and were found safe for dental use. Additionally, several of the components of all of the aforementioned devices/products including the **EDS Calculus Softener (TURBO-CR™)**, are also found in the FDA generally recognized as safe (GRAS) database. A search of the FDA MAUDE database yielded no adverse events for the cited predicate device, **SofScale (#K903163)**. We believe that prior use of components in legally marketed devices, the performance and biocompatibility data provided support the safety and effectiveness of the **EDS Calculus Softener (TURBO-CR™)** for the indicated use. *The device is provided non-sterile and does not contain fluoride or any whitening agents.*

The subject device is substantially equivalent to **SofScale (#K903163)** and **TheraSol Tartar Dissolver (510k exempt)** in that they are primarily comprised of chelating agents, detergents, sodium bicarbonate, gelling agents, and flavoring. The indications and directions for use for the subject device, **The EDS Calculus Softener (TURBO-CR™)**, and the primary predicate device, **SofScale (#K903163)** are substantially equivalent. Both devices are for professional use only. From a material composition indication for use, and equivalent dental application perspective, **TheraSol Tartar Dissolver** is substantially equivalent to the aforementioned devices despite some differences (**TheraSol Tartar Dissolver** is over the counter use).

The EDS Calculus Softener (TURBO-CR™) and the primary predicate device, **SofScale (#K903163)** are available as syringeable gels/pastes essentially designed for equivalent dental applications and have equivalent physical properties and performance specifications. The principal composition of **the EDS Calculus Softener (TURBO-CR™)** is substantially equivalent to **SofScale (#K903163)**. An additional reference predicate device includes **TheraSol Tartar Dissolver (510k exempt)** which contains specific chemical components that are equivalent to those found in **the EDS Calculus Softener (TURBO-CR™)**, providing evidence that these chemical components are safe and effective for medical device use.

Furthermore, the **EDS Calculus Softener (TURBO-CR™)** and **SofScale (#K903163)** have comparable delivery systems in that they are applied via syringe.

5.9. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as Follows: [807.92 (b)(1)]

The **EDS Calculus Softener (TURBO-CR™)** has undergone extensive bench and biocompatibility testing to provide evidence that the physical and chemical properties of the composition are substantially equivalent to the primary predicate device **SofScale (#K903163)**. Bench tests included:

- Softening of simulated dental calculus via Microindentation Hardness of Materials testing (ASTM E384-22)
- pH - ISO 11609:2017
- Viscosity - ISO 3219-2:2021

The legally marketed primary predicate device, **SofScale (#K903163)** shows that it is biocompatible and safe for the intended use. Additionally, the primary predicate device, **SofScale (#K903163)**, has been on the market for many years with a long history of safe clinical use. Since the chemical composition of **EDS Calculus Softener (TURBO-CR™)** is based on substantially chemically equivalent components, the biocompatibility testing data provides further evidence of biocompatibility and overall safety. The results of the biocompatibility testing shows that the **EDS Calculus Softener (TURBO-CR™)** is safe for the intended use and does not elicit any adverse reactions while exhibiting excellent tolerance by the muscosal tissue (*See 016_Section 15 - Biocompatibility*).

Safety:

Equivalence in safety to the predicate device is demonstrated by the results of biocompatibility tests performed according to ISO 10993, as follows:

- **ISO 7405:2018** - *Dentistry – Evaluation of biocompatibility of medical devices used in dentistry*
- **ISO 10993-1:2018** - *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.*
- **ISO 10993-5:2009 / (R)2014** - *Biological evaluation of medical devices - Part 5. Tests for in vitro Cytotoxicity.*

- **ISO 10993-10:2010 / (R)2014** - *Biological Evaluation of Medical Devices - Part 10: Tests For Irritation and Skin Sensitization.*
- **ISO 14971:2019 + A11:2021** - *Medical Devices - Application for risk management to medical devices.*

Performance:

Testing of physical properties according to the following standards was conducted:

- **ASTM E384-22** - *Standard Test Method for Microindentation Hardness of Materials*
- **ISO 11609:2017 and ANSI/ADA Standard No. 130** - *Dentistry – Dentifrices – Requirements, test methods and marking.*
- **ISO 3219-2:2021** - *Rheology – Part 2: General principles of rotational and oscillatory rheometry.*

5.10. Discussion of Clinical Tests Performed: [807.92 (b)(2)]

Not Applicable.

There was no clinical testing required to support the subject medical device, **EDS Calculus Softener (TURBO-CR™)**, as the indications for use are equivalent to the primary predicate device, **SofScale (K903163)**. These types of devices, including **the primary predicate device**, have been on the market for many years with a proven clinical safety and efficacy for the intended use. *A search of the FDA MAUDE database yielded no adverse events for the cited predicate device, SofScale (K903163).* The verification and validation testing of the device was found to be acceptable and supports the claims of substantial equivalence.

5.11. Statement of Substantial Equivalence: [807.92 (b)(3)]

The **EDS Calculus Softener (TURBO-CR™)** is substantially equivalent in terms of performance, indications for use, instructions for use, chemical mode of action, and biocompatibility to the cleared and marketed predicate devices, **SofScale (K903163) (primary predicate device)** and **Therasol Tartar Dissolver (510k exempt)**. *Any technological differences between the **EDS Calculus Softener (TURBO-CR™)** and the cited predicate devices do not raise any questions regarding the safety and effectiveness of the subject device.

The information provided in this submission supports the substantial equivalence to the predicate device(s) and that the subject device is safe and effective for the users/operators.