# DE NOVO CLASSIFICATION REQUEST FOR

# DentalMonitoring

## REGULATORY INFORMATION

FDA identifies this generic type of device as:

**Dental Image Analyzer**. A dental image analyzer is a prescription home use device that uses software intended to collect and analyze patient-specific, optical camera-based, intraoral images. The analyses are provided to dental health care professionals as an aid to diagnosis of oral health conditions and/or to monitor treatment progress.

**NEW REGULATION NUMBER:** 872.1770

**CLASSIFICATION:** Class II

**PRODUCT CODE:** SBC

## BACKGROUND

**DEVICE NAME:** DentalMonitoring

**SUBMISSION NUMBER:** DEN230035

**DATE DE NOVO RECEIVED:** 05/04/2023

**SPONSOR INFORMATION:**

Dental Monitoring SAS
Isabelle Puraye
75 rue de Tocqueville
Paris 75017

## INDICATIONS FOR USE

DentalMonitoring is a medical device software using image processing algorithms to analyze pictures of the oral cavity (hereinafter Scans). Scans are taken using the DM App, a smartphone, and the manufacturer's proprietary hardware products. Scans are taken by the patient, a non-healthcare professional, or a healthcare professional. The Scan is taken in healthcare facilities, such as a dental practice, or in a non-healthcare environment, such as the patient's own home. For some clinical parameters, DentalMonitoring requires a 3D Model. The product is designed to assist healthcare professionals in remotely monitoring orthodontic treatments and treatment progress. The results of DentalMonitoring are intended to be used as an aid in diagnosis and monitoring, not on a stand-alone basis for clinical decision-making. DentalMonitoring is indicated for use for patients over the age of 6 and reports results solely on permanent teeth.

DentalMonitoring can monitor the following clinical parameters:

- oral hygiene: dental plaque / food residue;
- soft tissue statement: gingival recession, black triangle;
- dental statement: closure of extraction space, tooth wear;
- alignment: closure of all anterior spaces; and
- dental occlusion:
    - in 2D Monitoring: midline deviation, overbite/open bite, overjet

- in 3D Monitoring: canine class, midline deviation, overbite/open bite, overjet

Additionally, the following clinical parameters specific to orthodontic treatment types or phases can be monitored using DentalMonitoring:

- for aligner treatments: tracking (seat/unseat), attachment loss, button loss;
- for braces: bracket debonding, tie loss, self-ligating clips, passive archwire and auxiliaries; and
- for thermoformed retainers: tracking (seat/unseat).

Based on an initial 3D Model provided by a healthcare professional, DentalMonitoring can also provide healthcare professionals with 3D Models representative of the patient's dentition and treatment progress. This device is a prescription device and is not intended for over-the-counter use

**LIMITATIONS**

DentalMonitoring should not be used on patients under the age of 6.

Dental Monitoring should not be used by patients presenting systemic conditions affective connective tissues not allowing them to open/close their buccal cavity sufficiently to acquire acceptable Scans.

The following population should be assisted by a third party to perform Scans:

- Children up to 12;
- Adults or children visually impaired;
- Adults or children hearing impaired;
- Or any condition that might prevent the patient from adopting the right position to take a Scan.

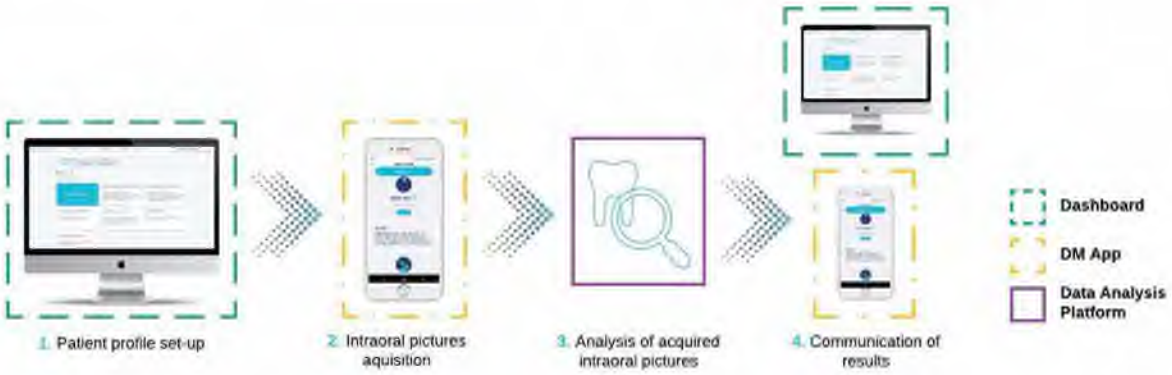
DentalMonitoring is not intended to replace standard practices for diagnosis or treatment. Final clinical decisions remain the sole responsibility of the healthcare professional. In order to establish a diagnosis, further examinations are required according to the current standard of care, such as dental radiographs and/or tactile examinations with instrumentation.

DentalMonitoring results are limited only to elements visible in the input Scans. DentalMonitoring does not provide results on non-visible elements such as potential interproximal and lingual cavities. DentalMonitoring does not provide results on lingual surfaces.

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

**DEVICE DESCRIPTION**

DentalMonitoring is a standalone software with embedded artificial intelligence comprising machine learning and locked neural network algorithms. The product is composed of these parts: the Dashboard, the DM App along with a DM Cheek Retractor and DM ScanBox, and the Data Analysis Platform.




The four steps are detailed below:

1. **Patient profile set-up**: The healthcare professional sets up the patient profile through a web- based interface, Dashboard, accessible at www.dental-monitoring.com/doctor. During the patient profile set-up, the healthcare professional is prompted to set up a Protocol in order to select the clinical parameters they wish to monitor in accordance with the patient's treatment. During the set-up, the healthcare professional also determines the appropriate frequency at which the patient should use the DM App to take pictures of their intraoral cavity.
2. **Intraoral pictures acquisition**: A set of pictures of the patient's intraoral cavity, hereinafter referred to as a Scan, is taken using the DM App along with a DM Cheek Retractor and DM ScanBox. The DM Cheek Retractor is an intraoral retraction device for the cheeks and lips to allow for sufficient space for image capture. The DM ScanBox is an extraoral holding apparatus for the smartphone that attaches to the DM Cheek Retractor. The DM App guides the user through the appropriate steps in order to obtain a complete Scan. This DM App is a mobile application installed on a smartphone; thus, the pictures are captured through the smartphone's main camera allowing the procedure to be totally non-invasive to the patient.

3. **Analysis of acquired intraoral pictures**: The Scan is processed through the Data Analysis Platform. The Data Analysis Platform includes a technical processing phase and clinical processing phase, the latter being a clinical analysis to determine if any event has occurred within the clinical parameters the healthcare professional has set up to be monitored. The Data Analysis Platform uses AI comprising image processing algorithms and neural networks.
4. **Communication of results**: Results of the analysis performed through the Data Analysis Platform are communicated to the healthcare professional through the Dashboard on one hand, and to the patient through the DM App on the other hand. Results are shared with the healthcare professional in an exhaustive fashion, providing them with detailed information. As for the patient, the results are communicated in accordance with the rules defined by the healthcare professional in the Protocol applied to the patient.

DentalMonitoring enables HCPs to adapt the use of the product according to their needs depending on each patient's orthodontic treatment. DentalMonitoring comprises two types of monitoring: 2D Monitoring and 3D Monitoring. Some clinical parameters are specific to either 2D Monitoring, or 3D Monitoring.

## SUMMARY OF NONCLINICAL/BENCH STUDIES

### BIOCOMPATIBILITY/MATERIALS

The DM Cheek Retractor were evaluated per ISO 10993-1 (2020): "Biological evaluation of medical devices Part 1: evaluation and testing with a risk management" and ISO 7405-2018 – Dentistry – evaluation of biocompatibility of medical devices used in dentistry. The proposed device passed cytotoxicity tests according to ISO 10993-5, skin sensitization according to ISO 10993-10, and irritation or intracutaneous reactivity according to ISO 10993-23.

### SOFTWARE

DentalMonitoring has a Modate Level of Concern (LOC). Appropriate software documentation for was provided in compliance with the FDA guidance document *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"* (issued in May 2005). Verification and validation (V&V) activities were performed and described at the unit and system level.

### CYBER SECURITY

DentalMonitoring approach to cybersecurity aligns with FDA's 2020 guidance titled, "Guidance on Cybersecurity For Medical Devices" The device also conforms to the cybersecurity requirements identified in Section 524B to the FD&C Act.

### PERFORMANCE TESTING - BENCH

AI/ML standalone testing

Standalone performance of each neural network and algorithm was evaluated. Neural networks and algorithms were classified into three families according to the outputs they provide. A unique protocol was established per family in order to perform the evaluation, with acceptance criteria adapted to each neural network and algorithm. DentalMonitoring comprises technical neural networks and algorithms as well as clinical neural networks and algorithms. The standalone testing showed acceptable performance of critical

features to demonstrate the device's ability to perform both it's clinical and technological functions.

## SUMMARY OF CLINICAL INFORMATION

The Sponsor provided data from a Clinical Investigation Program to support the clinical performance of DentalMonitoring.

**DentalMonitoring Clinical Investigation Program**

| Study type | Study code | Study name | Overview of targeted indications | List of (indication; monitoring plan) couples targeted |
|---|---|---|---|---|
| Retrospective | 21-001 | Retrospective | Qualitative indications with Reference Method compatible with DentalMonitoring picture set review | (dental plaque / food residue; 2D)<br>(gingival recession; 2D)<br>(black triangle; 2D)<br>(closure of extraction space; 2D)<br>(closure of all anterior spaces; 2D)<br>(tracking (seat/unseat); 2D)<br>(attachment loss; 2D)<br>(button loss; 2D)<br>(bracket debonding; 2D)<br>(tie loss; 2D)<br>(self-ligating clips; 2D) |

| Study type | Study code | Study name | Overview of targeted indications | List of (indication; monitoring plan) couples targeted |
|---|---|---|---|---|
| Prospective | 21-002 | Occlusion | Occlusion indications | (canine class; 3D)<br>(midline deviation; 2D)<br>(midline deviation; 3D)<br>(overbite/open bite; 2D)<br>(overbite/open bite; 3D)<br>(overjet; 2D)<br>(overjet; 3D) |
| Prospective | 21-003 | Archwire & Auxiliaries | Passive archwire and auxiliaries indication | (passive archwire and auxiliaries; 2D)<br>(passive archwire and auxiliaries; 3D) |
| Prospective | 21-004 | Updated 3D Model | Updated 3D Model indication | (Updated 3D Model; 3D) |

*Retrospective study*

DentalMonitoring evaluated the qualitative indications that were able to have the Reference Method used solely DentalMonitoring picture sets (= Scan). The study was performed using Scans retrospectively collected and involved a total of 15 US orthodontists.

The Reference Method results were generated as follow:

- Scans were reviewed by a panel of three independent orthodontists with an assessment done per tooth / interdental space.
- In case of non-dominant results, a consensus was established by the same group of three independent orthodontists. Dominant results and result of the consensus review were merged in order to generate the Reference Method initial outcome.
- Per indication, results presenting discrepancies between the Reference Method and the Candidate Method, *i.e.,* False Positive results and False Negative results, were reviewed by one of the orthodontists among the 15 that took part in the study.

Data was collected in order to qualify the patient demographics.

Results per indication

*Dental plaque / food residue*

| Characteristic | # (%) |
|---|---|
| **Age group** | |
| 12- 22 years of age | 367 (49.5%) |
| ≥ 22 years of age | 4 (0.6%) |
| ≤12 years old | 369 (49.8%) |
| Unknown | 1 (0.1%) |
| **Location** | |
| Central | 420 (56.7%) |
| East Coast | 209 (28.2%) |
| US - Other | 5 (0.7%) |
| West Coast | 60 (8.1%) |
| Western | 30 (4.0%) |
| Out of US | 17 (2.3%) |
| **Treatment type** | |
| Aligners | 415 (56.0%) |
| Brackets - Ceramic | 9 (1.2%) |
| Brackets - Self-ligating | 128 (17.3%) |
| Brackets - Traditional | 135 (18.2%) |
| Mixed | 32 (4.3%) |
| None | 5 (0.7%) |
| Retainers | 17 (2.3%) |

**Final comparison between DentalMonitoring and Reference**

| | | Reference Result | | |
|---|---|---|---|---|
| | | Positive (Noticeable or Slight) | Negative | Total |
| DM Result | Positive (Noticeable or Slight) | 1,874 | 356 | 2,230 |
| | Negative | 362 | 2,472 | 2,834 |
| | Total | 2,236 | 2,828 | 5,064 |

**Final study results for dental plaque / food residue**

| | Result | 95% CI Lower Bound | 95% CI Upper Bound |
|---|---|---|---|
| Sensitivity | 82.5% | 79.9% | 84.8% |
| Specificity | 83.2% | 80.5% | 85.5% |

Scans were taken using the following phone manufacturers: Apple, Samsung, Google, Motorola, LG, OnePlus, Huawei, Xiaomi, Essential Phone

*Gingival recession*

| Characteristic | # (%) |
|---|---|
| **Age group** | |
| 12- 22 years of age | 205 (51.3%) |
| ≥ 22 years of age | 194 (48.5%) |
| ≤12 years old | 1 (0.2%) |
| **Location** | |
| Central | 236 (59%) |
| East Coast | 96 (24%) |
| West Coast | 30 (7.5%) |
| US - Other | 5 (1.2%) |
| Out of US | 12 (3%) |
| Western | 21 (5.3%) |
| **Treatment type** | |
| Aligners | 205 (51.2%) |
| Retainers | 17 (4.2%) |
| Brackets - Ceramic | 7 (1.8%) |
| Brackets - Self-ligating | 68 (17%) |
| Brackets - Traditional | 82 (20.5%) |
| Mixed treatment | 20 (5%) |
| No treatment | 1 (0.3%) |

**Final comparison between DentalMonitoring and Reference**

| | | Reference Result | | |
|---|---|---|---|---|
| | | **Positive** | **Negative** | **Total** |
| **DM Result** | **Positive** | 77 | 18 | 95 |
| | **Negative** | 19 | 756 | 775 |
| | **Total** | 96 | 774 | 870 |

**Final study results for gingival recession**

| | Result | 95% CI Lower Bound | 95% CI Upper Bound |
|---|---|---|---|
| **Sensitivity** | 79.9% | 70.3% | 86.9% |
| **Specificity** | 97.4% | 95.8% | 98.4% |

Scans were taken using the following phone manufacturers: Apple, Samsung, Google, Motorola, LG, Huawei, Essential Phone, Kyocera, OnePlus, and Wiko.

*Black triangle*

| Characteristic | # (%) |
|---|---|
| **Age group** | |
| 12 - 22 years of age | 233 (62%) |
| ≥ 22 years of age | 140 (37.2%) |
| ≤ 12 years old | 3 (0.8%) |
| **Location** | |
| Central | 231 (61.4%) |
| East Coast | 97 (25.8%) |
| West Coast | 23 (6.1%) |
| Out of US | 7 (1.9%) |
| Western | 14 (3.7%) |
| US-Other | 4 (1.1%) |
| **Treatment type** | |
| Aligners | 166 (44.2%) |
| Retainers | 12 (3.2%) |
| Brackets - Ceramic | 9 (2.4%) |
| Brackets - Self-ligating | 79 (21%) |
| Brackets - Traditional | 87 (23.1%) |
| Mixed treatment | 21 (5.6%) |
| No treatment | 2 (0.5%) |

**Final comparison between DentalMonitoring and Reference**

| | | Reference Result | | |
|---|---|---|---|---|
| | | **Positive** | **Negative** | **Total** |
| **DM Result** | **Positive** | 179 | 12 | 191 |
| | **Negative** | 40 | 906 | 946 |
| | **Total** | 219 | 918 | 1,137 |

**Final study results for black triangle**

| | Result | 95% CI Lower Bound | 95% CI Upper Bound |
|---|---|---|---|
| **Sensitivity** | 81.0% | 73.9% | 86.5% |
| **Specificity** | 98.4% | 96.9% | 99.2% |

Scans were taken using the following phone manufacturers: Apple, Samsung, Google, Motorola, LG, OnePlus, Huawei, and Xiaomi.

*Closure of extraction space*

| Characteristic | # (%) |
|---|---|
| **Age group** | |
| 12 -22 years of age | 105 (41.3%) |
| ≥ 22 years of age | 5 (2.0%) |
| ≤ 12 years old | 142 (55.9%) |
| Unknown | 2 (0.8%) |
| **Location** | |
| Central | 137 (53.9%) |
| East Coast | 67 (26.4%) |
| US - Other | 6 (2.4%) |
| West Coast | 25 (9.8%) |
| Western | 11 (4.3%) |
| out of US | 8 (3.2%) |
| **Treatment type** | |
| Aligners | 125 (49.2%) |
| Brackets - Ceramic | 3 (1.2%) |
| Brackets - Self-ligating | 55 (21.7%) |
| Brackets - Traditional | 44 (17.3%) |
| Mixed treatment | 16 (6.3%) |
| None | 1 (0.4%) |
| Retainers | 10 (3.9%) |

**Final comparison between DentalMonitoring and Reference**

| | | Reference Result | | |
|---|---|---|---|---|
| | | **Positive** | **Negative** | **Total** |
| **DM Result** | **Positive** | 198 | 24 | 222 |
| | **Negative** | 0 | 256 | 256 |
| | **Total** | 198 | 280 | 478 |

**Final study results for closure of extraction space**

| | Result | 95% CI Lower Bound | 95% CI Upper Bound |
|---|---|---|---|
| **Sensitivity** | 100.0% | 94.2% | / |
| **Specificity** | 91.8% | 87.2% | 94.9% |

Scans were taken using the following phone manufacturers: Apple, Samsung, LG, Google, Motorola, Essential Phone, Huawei, and Wiko.

*Tooth wear*

| Characteristic | # (%) |
|---|---|
| **Age group** | |
| 12 - 22 years of age | 200 (54.8%) |
| ≥ 22 years of age | 164 (44.9%) |
| ≤ 12 years old | 1 (0.3%) |
| **Location** | |
| Central | 232 (63.6%) |
| East Coast | 83 (22.7%) |
| West Coast | 22 (6.0%) |
| Western | 14 (3.8%) |
| Out of US | 11 (3.0%) |
| US-Other | 3 (0.8%) |
| **Treatment type** | |
| Aligners | 162 (44.4%) |
| Brackets - Ceramic | 5 (1.4%) |
| Brackets - Self-ligating | 74 (20.3%) |
| Brackets - Traditional | 88 (24.1%) |
| Mixed | 1 (0.3%) |
| Mixed treatment | 22 (6%) |
| None | 1 (0.3%) |
| Retainers | 12 (3.3%) |

**Final comparison between DentalMonitoring and Reference**

| | | Reference Result | | |
|---|---|---|---|---|
| | | **Positive** | **Negative** | **Total** |
| **DM Result** | **Positive** | 89 | 21 | 110 |
| | **Negative** | 13 | 943 | 956 |
| | **Total** | 102 | 964 | 1,066 |

**Final study results for tooth wear**

| | **Result** | **95% CI Lower Bound** | **95% CI Upper Bound** |
|---|---|---|---|
| **Sensitivity** | 84.5% | 74.1% | 91.2% |
| **Specificity** | 97.0% | 94.9% | 98.2% |

Scans were taken using the following phone manufacturers: Apple, Samsung, LG, Google, Motorola, Huawei, and Essential Phone.

*Closure of all anterior spaces*

| Characteristic | # (%) |
|---|---|
| **Age group** | |
| 12 - 22 years of age | 297 (57.5%) |
| ≥ 22 years of age | 213 (41.3%) |
| ≤ 12 years old | 4 (0.8%) |
| Unknown | 2 (0.4%) |
| **Location** | |
| Central | 307 (59.5%) |
| East Coast | 131 (25.4%) |
| West Coast | 38 (7.4%) |
| Out of US | 10 (1.9%) |
| US - Other | 4 (0.8%) |
| Western | 26 (5.0%) |
| **Treatment type** | |
| Aligners | 248 (48.1%) |
| Brackets - Ceramic | 6 (1.2%) |
| Brackets - Self-ligating | 114 (22.1%) |
| Brackets - Traditional | 106 (20.5%) |
| Mixed | 2 (0.4%) |
| Mixed treatment | 21 (4.1%) |
| None | 6 (1.2%) |
| Retainers | 13 (2.5%) |

**Final comparison between DentalMonitoring and Reference**

| | | Reference Result | | |
|---|---|---|---|---|
| | | **Positive** | **Negative** | **Total** |
| **DM Result** | **Positive** | 180 | 88 | 268 |
| | **Negative** | 3 | 442 | 445 |
| | **Total** | 183 | 530 | 713 |

**Final study results for anterior space closure**

| | Result | 95% CI Lower Bound | 95% CI Upper Bound |
|---|---|---|---|
| **Sensitivity** | 98.3% | 94.9% | 99.5% |
| **Specificity** | 83.3% | 79.9% | 86.3% |

Scans were taken using the following phone manufacturers: Apple, Samsung, Google, Motorola, LG, Huawei, T-Mobile, Essential Phone, and Xiaomi.

*Tracking (seat/unseat)*

| Characteristic | # (%) |
|---|---|
| **Age group** | |
| ]12; 22[ years of age | 279 (44.8%) |
| ≥ 22 years of age | 332 (53.3%) |
| ≤ 12 years old | 9 (1.4%) |
| Unknown | 3 (0.5%) |
| **Location** | |
| Central | 286 (45.9%) |
| East Coast | 192 (30.8%) |
| out of US | 17 (2.7%) |
| US - Other | 8 (1.3%) |
| West Coast | 85 (13.7%) |
| Western | 35 (5.6%) |
| **Treatment type** | |
| Aligners | 581 (93.3%) |
| Brackets - Traditional | 4 (0.6%) |
| Mixed | 1 (0.2%) |
| Mixed treatment | 9 (1.4%) |
| Retainers | 28 (4.5%) |

Clinical performances are expressed as two different Sensitivities and Specificities since the parameter outputs three levels.

- Sensitivity and Specificity of the product in its ability to detect people with the evaluated condition from people without; and
- Sensitivity and Specificity of the product in its ability to discriminate the evaluated condition at a slight level from a noticeable level

**Detection of patients with the evaluated condition (presence/absence)**

| | | Reference Result | | |
|---|---|---|---|---|
| | | Positive (Noticeable or Slight) | Negative | Total |
| DM Result | Positive (Noticeable or Slight) | 1,360 | 165 | 1,525 |
| | Negative | 101 | 1,697 | 1,798 |
| | Total | 1,461 | 1,862 | 3,323 |

| | Result | 95% CI Lower Bound | 95% CI Upper Bound |
|---|---|---|---|
| Sensitivity | 93.2% | 91.3% | 94.7% |
| Specificity | 86.2% | 83.4% | 88.6% |

**Detection of patients with the level of the condition (slight/noticeable)**

| | | Reference Result | | |
|---|---|---|---|---|
| | | Noticeable | Slight | Total |
| DM Result | Noticeable | 193 | 99 | 292 |
| | Slight | 18 | 1,050 | 1,068 |
| | Total | 211 | 1,149 | 1,360 |

| | Result | 95% CI Lower Bound | 95% CI Upper Bound |
|---|---|---|---|
| Sensitivity | 91.1% | 85.9% | 94.5% |
| Specificity | 90.5% | 87.7% | 92.7% |

Scans were taken using the following phone manufacturers: Apple, Samsung, Google, LG, Motorola, OnePlus, Huawei, Essential Phone, Wiko, and Xiaomi.

*Attachment loss*

| Characteristic | # (%) |
|---|---|
| **Age group** | |
| ]12; 22[ years of age | 146 (41.9%) |
| ≥ 22 years of age | 200 (57.5%) |
| ≤ 12 years old | 1 (0.3%) |
| Unknown | 1 (0.3%) |
| **Location** | |
| Central | 171 (49.1%) |
| East Coast | 109 (31.3%) |
| West Coast | 39 (11.2%) |
| US - Other | 4 (1.2%) |
| Out of US | 8 (2.3%) |
| Western | 17 (4.9%) |
| **Treatment type** | |
| Aligners | 330 (94.8%) |
| Retainers | 8 (2.3%) |
| Brackets - Traditional | 4 (1.2%) |
| Mixed treatment | 6 (1.7%) |

**Final comparison between DentalMonitoring and Reference**

| | | Reference Result | | |
|---|---|---|---|---|
| | | **Positive** | **Negative** | **Total** |
| **DM Result** | **Positive** | 183 | 0 | 183 |
| | **Negative** | 3 | 579 | 582 |
| | **Total** | 186 | 579 | 765 |

**Final study results for attachment loss**

| | **Result** | **95% CI Lower Bound** | **95% CI Upper Bound** |
|---|---|---|---|
| **Sensitivity** | 98.2% | 94.3% | 99.4% |
| **Specificity** | 100.0% | 98.7% | / |

Scans were taken using the following phone manufacturers: Apple, Samsung, Google, Motorola, LG, Xiaomi, OnePlus, and Essential Phone.

*Button loss*

| Characteristic | # (%) |
|---|---|
| **Age group** | |
| ]12; 22[ years of age | 200 (52.5%) |
| ≥ 22 years of age | 158 (41.5%) |
| ≤ 12 years old | 20 (5.2%) |
| Unknown | 3 (0.8%) |
| **Location** | |
| Central | 138 (36.2%) |
| East Coast | 125 (32.8%) |
| West Coast | 92 (24.1%) |
| Out of US | 4 (1%) |
| Western | 16 (4.2%) |
| US - Other | 6 (1.6%) |
| **Treatment type** | |
| Aligners | 370 (97.1%) |
| Retainers | 1 (0.3%) |
| Brackets - Ceramic | 1 (0.3%) |
| Brackets - Traditional | 3 (0.8%) |
| Mixed treatment | 6 (1.6%) |

**Final comparison between DentalMonitoring and Reference**

| | | Reference Result | | |
|---|---|---|---|---|
| | | **Positive** | **Negative** | **Total** |
| **DM Result** | **Positive** | 127 | 5 | 132 |
| | **Negative** | 2 | 525 | 527 |
| | **Total** | 129 | 530 | 659 |

**Final study results for button loss**

| | Result | 95% CI Lower Bound | 95% CI Upper Bound |
|---|---|---|---|
| **Sensitivity** | 98.4% | 94.0% | 99.6% |
| **Specificity** | 99.0% | 96.9% | 99.7% |

Scans were taken using the following phone manufacturers: Apple, Samsung, LG, Motorola, Google, and Huawei.

*Bracket debonding*

| Characteristic | # (%) |
|---|---|
| **Age group** | |
| ]12; 22[ years of age | 270 (71.3%) |
| ≥ 22 years of age | 107 (28.2%) |
| ≤ 12 years old | 2 (0.5%) |
| **Location** | |
| Central | 291 (76.8%) |
| East Coast | 60 (15.8%) |
| West Coast | 16 (4.2%) |
| Out of US | 1 (0.3%) |
| Western | 11 (2.9%) |
| **Treatment type** | |
| Aligners | 1 (0.3%) |
| Brackets - Ceramic | 10 (2.5%) |
| Brackets - Self-ligating | 171 (45.1%) |
| Brackets - Traditional | 150 (39.6%) |
| Mixed treatment | 45 (11.9%) |
| None | 1 (0.3%) |
| Retainers | 1 (0.3%) |

**Final comparison between DentalMonitoring and Reference**

| | | Reference Result | | |
|---|---|---|---|---|
| | | **Positive** | **Negative** | **Total** |
| **DM Result** | **Positive** | 127 | 2 | 129 |
| | **Negative** | 2 | 528 | 530 |
| | **Total** | 129 | 530 | 659 |

**Final study results for bracket debonding**

| | Result | 95% CI Lower Bound | 95% CI Upper Bound |
|---|---|---|---|
| **Sensitivity** | 98.4% | 93.8% | 99.6% |
| **Specificity** | 99.6% | 98.5% | 99.9% |

Scans were taken using the following phone manufacturers: Apple, Samsung, Google, LG, Motorola, One Plus.

*Tie loss*

| Characteristic | # (%) |
|---|---|
| **Age group** | |
| ]12; 22[ years of age | 240 (77.4%) |
| ≥ 22 years of age | 66 (21.3%) |
| ≤ 12 years old | 4 (1.3%) |
| **Location** | |
| Central | 255 (82.2%) |
| East Coast | 39 (12.6%) |
| West Coast | 10 (3.2%) |
| Western | 3 (1.0%) |
| Out of US | 3 (1.0%) |
| **Treatment type** | |
| Aligners | 1 (0.3%) |
| Brackets - Ceramic | 13 (4.2%) |
| Brackets - Self-ligating | 5 (1.6%) |
| Brackets - Traditional | 267 (86.2%) |
| Mixed | 1 (0.3%) |
| Mixed treatment | 23 (7.4%) |

**Final comparison between DentalMonitoring and Reference**

| | | Reference Result | | |
|---|---|---|---|---|
| | | **Positive** | **Negative** | **Total** |
| **DM Result** | **Positive** | 111 | 15 | 126 |
| | **Negative** | 7 | 520 | 527 |
| | **Total** | 118 | 535 | 653 |

**Final study results for tie loss**

| | Result | 95% CI Lower Bound | 95% CI Upper Bound |
|---|---|---|---|
| **Sensitivity** | 93.3% | 85.7% | 97.0% |
| **Specificity** | 96.5% | 94.0% | 98.0% |

Scans were taken using the following phone manufacturers: Apple, Samsung, Motorola, LG, Google.

*Self-ligating clips*

| Characteristic | # (%) |
|---|---|
| **Age group** | |
| ]12; 22[ years of age | 217 (66.8%) |
| ≥ 22 years of age | 103 (31.7%) |
| ≤ 12 years old | 5 (1.5%) |
| **Location** | |
| Central | 225 (69.3%) |
| East Coast | 69 (21.2%) |
| Western | 16 (4.9%) |
| West Coast | 12 (3.7%) |
| Out of US | 3 (0.9%) |
| **Treatment type** | |
| Brackets - Ceramic | 5 (1.5%) |
| Brackets - Self-ligating | 262 (80.6%) |
| Brackets - Traditional | 21 (6.5%) |
| Mixed | 2 (0.6%) |
| Mixed treatment | 35 (10.8%) |

**Final comparison between DentalMonitoring and Reference**

| | | Reference Result | | |
|---|---|---|---|---|
| | | **Positive** | **Negative** | **Total** |
| **DM Result** | **Positive** | 71 | 48 | 119 |
| | **Negative** | 7 | 521 | 528 |
| | **Total** | 78 | 569 | 647 |

**Final study results for self-ligating clip**

| | Result | 95% CI Lower Bound | 95% CI Upper Bound |
|---|---|---|---|
| **Sensitivity** | 91.1% | 82.5% | 95.7% |
| **Specificity** | 88.3% | 84.1% | 91.5% |

Scans were taken using the following phone manufacturers: Apple, Samsung, Google, LG, Motorola, Huawei, Kyocera, and OnePlus.

*Occlusion study*

DentalMonitoring evaluated the occlusion indications using 3D Models acquired with intraoral scanners as input data to the Reference Method. The study was performed using data collected prospectively. The study involved four sites located in the United States: three sites for patient enrollment and one site for generation of the Reference Method results.

The Reference Method results were generated by measuring the occlusion parameters undergoing evaluation on 3D Models of the patients enrolled in the study. Measurements were done manually and performed in three replicates using a CAD/CAM software.

Analysis was performed according to "*Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Clinical and Laboratory Standards Institute guideline"*, EP09c - Third Edition, 2018. Analysis comprised using a :Passing-Bablok regression analysis, including plots of Candidate Method verses Reference Method to calculate the slope, intercept, and correlation coefficient of the plot. Bias at levels of interest per study group were computed at the levels of interest and confidence intervals were calculated with the 95% Bootstrapping.

Data was collected in order to qualify the patient demographics.

Results per indication

*Canine class – 3D Monitoring*

A total of 215 patients rendering 297 results were included in the analysis. One patient could render multiple results corresponding to left canine class and right canine class.

| Characteristic | # (%) |
|---|---|
| **Gender** | |
| Male | 153 (71.2%) |
| Female | 62 (28.8%) |
| **Age group** | |
| [6; 12] years of age | 23 (10.7%) |
| ]12; 22[ years of age | 75 (34.9%) |
| ≥ 22 years of age | 117 (54.4%) |
| **Race*** | |
| American Indian or Alaska Native | 13 (6.0%) |
| Asian | 10 (4.7%) |
| Black or African American | 12 (5.6%) |
| Native Hawaiian or Other Pacific Islander | 0 (0.0%) |
| White | 168 (78.1%) |
| Unknown race | 14 (6.5%) |
| **Ethnicity** | |
| Spanish origin | 32 (14.9%) |
| Not Hispanic or Latino | 183 (85.1%) |
| **Income of the household (annual)** | |
| Less than $19,999 | 9 (4.2%) |
| $20,000-$37,999 | 11 (5.1%) |
| $38,000-$44,999 | 3 (1,4%) |
| $45,000-$54,999 | 7 (3.3%) |
| $55,000-$64,999 | 14 (6.5%) |
| $65,000-$74,999 | 11 (5.1%) |
| $75,000-$99,999 | 25 (11.6%) |
| $100,000 or more | 69 (32.1%) |
| Unknown | 66 (30.7%) |
| **Level of education** | |
| < Highschool Diploma | 84 (39.1%) |
| Highschool Diploma or Equivalent | 38 (17.6%) |
| Associates Degree | 25 (11.6%) |
| Bachelors Degree | 44 (20.5%) |
| Masters Degree | 20 (9.3%) |
| Doctoral Degree | 4 (1.9%) |

**Of note, the race does not correspond to the total number of patients as some patients with mixed races were included in the analysis.*

| | |
|---|---|
| **Slope** | 0.95<br>[0.92, 0.98] |
| **Intercept** | -0.10 mm<br>[-0.14, -0.04]* |
| **Bias at 0.00 mm** | -0.10 mm<br>[-0.18, 0.00]* |
| **Bias at -2.00 mm** | -0.3%<br>[-4.9, 6.8] |
| **Bias at 3.00 mm** | -9.4 %<br>[-12.9, -5.3] |
| **Bias at 5.00 mm** | -7.9 %<br>[-11.0, -4.4] |

*Of note, the difference between the two 95% CI is due to the fact that the bootstrap is used for bias CI calculation, whereas for the intercept and slope it is the standard CI calculation linked to Passing-Bablok regression that is used.

*Midline deviation – 2D Monitoring*

A total of 277 patients rendering 277 results were included in the analysis. One patient rendered a unique result.

| Characteristic | # (%) |
|---|---|
| **Gender** | |
| Male | 191 (69.0%) |
| Female | 86 (31.0%) |
| **Age group** | |
| [6; 12] years of age | 36 (13.0%) |
| ]12; 22[ years of age | 94 (33.9%) |
| ≥ 22 years of age | 147 (53.1%) |
| **Race*** | |
| American Indian or Alaska Native | 12 (4.3%) |
| Asian | 11 (4.0%) |
| Black or African American | 26 (9.4%) |
| Native Hawaiian or Other Pacific Islander | 0 (0.0%) |
| White | 215 (77.6%) |
| Unknown race | 16 (5.7%) |
| **Ethnicity** | |
| Spanish origin | 37 (13.4%) |
| Not Hispanic or Latino | 240 (86.6%) |
| **Income of the household (annual)** | |
| Less than $19,999 | 12 (4.3%) |
| $20,000-$37,999 | 14 (5.1%) |
| $38,000-$44,999 | 6 (2.2%) |
| $45,000-$54,999 | 7 (2.5%) |
| $55,000-$64,999 | 14 (5.1%) |
| $65,000-$74,999 | 18 (6.5%) |
| $75,000-$99,999 | 29 (10.5%) |
| $100,000 or more | 100 (36.1%) |
| Unknown | 77 (27.7%) |
| **Level of education** | |
| < Highschool Diploma | 100 (36.1%) |
| Highschool Diploma or Equivalent | 54 (19.5%) |
| Associates Degree | 31 (11.2%) |
| Bachelors Degree | 58 (20.9%) |
| Masters Degree | 29 (10.5%) |
| Doctoral Degree | 5 (1.8%) |

**Of note, the race does not correspond to the total number of patients as some patients with mixed races were included in the analysis.*

| | |
|---|---|
| **Slope** | 0.93<br>[0.89, 0.97] |
| **Intercept** | 0.0 mm *(-0.03)*<br>[0.0, 0.0] *[-0.05, 0.01]** |
| **Bias at 0.0 mm** | 0.0 mm *(0.03)*<br>[0.0, 0.0] *[-0.07, 0.03]** |
| **Bias at -2.0 mm** | 5.3%<br>[-0.8, 10.7] |
| **Bias at 2.0 mm** | -8.9%<br>[-13.6, -3.2] |

*Of note, the difference between the two 95% CI is due to the fact that the bootstrap is used for bias CI calculation, whereas for the intercept and slope it is the standard CI calculation linked to Passing-Bablok regression that is used.

*Midline deviation – 3D Monitoring*

A total of 291 patients rendering 294 results were included in the analysis. One patient rendered a unique result.

| Characteristic | # (%) |
|---|---|
| **Gender** | |
| Male | 200 (68.7%) |
| Female | 91 (31.3%) |
| **Age group** | |
| [6; 12] years of age | 47 (16.2%) |
| ]12; 22[ years of age | 98 (33.6%) |
| ≥ 22 years of age | 146 (50.2%) |
| **Race*** | |
| American Indian or Alaska Native | 12 (4.1%) |
| Asian | 6 (2.1%) |
| Black or African American | 26 (8.9%) |
| Native Hawaiian or Other Pacific Islander | 0 (0.0%) |
| White | 224 (77.0%) |
| Unknown race | 30 (10.3%) |
| **Ethnicity** | |
| Spanish origin | 38 (13.1%) |
| Not Hispanic or Latino | 253 (86.9%) |
| **Income of the household (annual)** | |
| Less than $19,999 | 12 (4.1%) |
| $20,000-$37,999 | 16 (5.5%) |
| $38,000-$44,999 | 6 (2.1%) |
| $45,000-$54,999 | 7 (2.4%) |
| $55,000-$64,999 | 15 (5.2%) |
| $65,000-$74,999 | 18 (6.2%) |
| $75,000-$99,999 | 33 (11.3%) |
| $100,000 or more | 101 (34.7%) |
| Unknown | 83 (28.5%) |
| **Level of education** | |
| < Highschool Diploma | 109 (37.5%) |
| Highschool Diploma or Equivalent | 55 (18.8%) |
| Associates Degree | 36 (12.4%) |
| Bachelors Degree | 61 (21.0%) |
| Masters Degree | 28 (9.6%) |
| Doctoral Degree | 2 (0.7%) |

**Of note, the race does not correspond to the total number of patients as some patients with mixed races were included in the analysis.*

| | |
|---|---|
| **Slope** | 0.98<br>[0.96, 1.00] |
| **Intercept** | -0.01 mm<br>[-0.02, 0.01]* |
| **Bias at 0.0 mm** | -0.01 mm<br>[-0.03, 0.02]* |
| **Bias at -2.00 mm** | 2.0 %<br>[-0.5, 4.8] |
| **Bias at 2.00 mm** | -2.7%<br>[-5.2, -0.4] |

*Of note, the difference between the two 95% CI is due to the fact that the bootstrap is used for bias CI calculation, whereas for the intercept and slope it is the standard CI calculation linked to Passing-Bablok regression that is used.*Interpretation of bias signs*

*Overbite / open bite – 2D Monitoring*

A total of 285 patients rendering 301 results were included in the analysis. One patient could render multiple results corresponding to both central incisor couples.

| Characteristic | # (%) |
|---|---|
| **Gender** | |
| Male | 194 (68.1%) |
| Female | 91 (31.9%) |
| **Age group** | |
| [6; 12] years of age | 36 (12.7%) |
| ]12; 22[ years of age | 87 (30.5%) |
| ≥ 22 years of age | 162 (56.8%) |
| **Race*** | |
| American Indian or Alaska Native | 10 (3.5%) |
| Asian | 11 (3.9%) |
| Black or African American | 32 (11.2%) |
| Native Hawaiian or Other Pacific Islander | 0 (0.0%) |
| White | 216 (75.8%) |
| Unknown race | 21 (7.4%) |
| **Ethnicity** | |
| Spanish origin | 36 (12.6%) |
| Not Hispanic or Latino | 249 (87.4%) |
| **Income of the household (annual)** | |
| Less than $19,999 | 11 (3.9%) |
| $20,000-$37,999 | 16 (5.5%) |
| $38,000-$44,999 | 8 (2,8%) |
| $45,000-$54,999 | 7 (2.5%) |
| $55,000-$64,999 | 12 (4.2%) |
| $65,000-$74,999 | 19 (6.7%) |
| $75,000-$99,999 | 33 (11.6%) |
| $100,000 or more | 103 (36.1%) |
| Unknown | 76 (26.7%) |
| **Level of education** | |
| < Highschool Diploma | 102 (35.8%) |
| Highschool Diploma or Equivalent | 51 (17.9%) |
| Associates Degree | 31 (10.9%) |
| Bachelors Degree | 65 (22.8%) |
| Masters Degree | 32 (11.2%) |
| Doctoral Degree | 4 (1.4%) |

**Of note, the race does not correspond to the total number of patients as some patients with mixed races were included in the analysis.*

| | |
|---|---|
| **Slope** | 0.95<br>95% CI = [0.91, 0.99] |
| **Intercept** | 0.2 mm<br>95% CI = [0.1, 0.3]* |
| **Bias at 0.0 mm** | 0.2 mm<br>95% CI = [0.0, 0.3]* |
| **Bias at 3.0 mm** | 0.9%<br>95% CI = [-2.4, 3.7] |
| **Bias at 5.0 mm** | -1.3 %<br>95% CI = [-4.1, 1.2] |
| **Bias at 7.0 mm** | -2.3 %<br>95% CI = [-5.5, 0.5] |

*Of note, the difference between the two 95% CI is due to the fact that the bootstrap is used for bias CI calculation, whereas for the intercept and slope it is the standard CI calculation linked to Passing-Bablok regression that is used.

*Overbite / open bite – 3D Monitoring*

A total of 287 patients rendering 298 results were included in the analysis. One patient could render multiple results corresponding to both central incisor couples.

| Characteristic | # (%) |
|---|---|
| **Gender** | |
| Male | 90 (31.4%) |
| Female | 197 (68.6%) |
| **Age group** | |
| [6; 12] years of age | 42 (14.6%) |
| ]12; 22[ years of age | 89 (31%) |
| ≥ 22 years of age | 156 (54.4%) |
| **Race*** | |
| American Indian or Alaska Native | 10 (3.5%) |
| Asian | 10 (3.5%) |
| Black or African American | 31 (10.8%) |
| Native Hawaiian or Other Pacific Islander | 0 (0.0%) |
| White | 217 (75.6%) |
| Unknown race | 26 (9.9%) |
| **Ethnicity** | |
| Spanish origin | 37 (12.9%) |
| Not Hispanic or Latino | 250 (87.1%) |
| **Income of the household (annual)** | |
| Less than $19,999 | 11 (3.8%) |
| $20,000-$37,999 | 17 (5.9%) |
| $38,000-$44,999 | 8 (2.8%) |
| $45,000-$54,999 | 7 (2.4%) |
| $55,000-$64,999 | 12 (4.2%) |
| $65,000-$74,999 | 20 (7.0%) |
| $75,000-$99,999 | 32 (11.2%) |
| $100,000 or more | 102 (35.5%) |
| Unknown | 78 (27.2%) |
| **Level of education** | |
| < Highschool Diploma | 101 (35.2%) |
| Highschool Diploma or Equivalent | 51 (17.8%) |
| Associates Degree | 33 (11.5%) |
| Bachelors Degree | 71 (24.7%) |
| Masters Degree | 29 (10.1%) |
| Doctoral Degree | 2 (0.7%) |

**Of note, the race does not correspond to the total number of patients as some patients with mixed races were included in the analysis.*

| | |
|---|---|
| **Slope** | 0.97<br>95% CI = [0.96, 0.99] |
| **Intercept** | 0.01 mm<br>95% CI= [-0.02, 0.05]* |
| **Bias at 0.00 mm** | 0.01 mm<br>95% CI = [-0.03, 0.05]* |
| **Bias at 3.00 mm** | -2.2%<br>95% CI = [-3.1, -1.5] |
| **Bias at 5.00 mm** | -2.4%<br>95% CI = [-3.3, -1.4] |
| **Bias at 7.00 mm** | -2.4%<br>95% CI = [-3.5, -1.3] |

*Of note, the difference between the two 95% CI is due to the fact that the bootstrap is used for bias CI calculation, whereas for the intercept and slope it is the standard CI calculation linked to Passing-Bablok regression that is used.

*Overjet – 2D Monitoring*

A total of 208 patients rendering 245 results were included in the analysis. One patient could render multiple results corresponding to both central incisor couples.

| Characteristic | # (%) |
|---|---|
| **Gender** | |
| Male | 69 (33.2%) |
| Female | 139 (66.8%) |
| **Age group** | |
| [6; 12] years of age | 34 (16.3%) |
| ]12; 22[ years of age | 70 (33.7%) |
| ≥ 22 years of age | 104 (50.0%) |
| **Race*** | |
| American Indian or Alaska Native | 9 (4.3%) |
| Asian | 8 (3.8%) |
| Black or African American | 23 (11.1%) |
| Native Hawaiian or Other Pacific Islander | 0 (0.0%) |
| White | 159 (76.5%) |
| Unknown race | 16 (7.7%) |
| **Ethnicity** | |
| Spanish origin | 32 (15.4%) |
| Not Hispanic or Latino | 176 (84.6%) |
| **Income of the household (annual)** | |
| Less than $19,999 | 10 (4.8%) |
| $20,000-$37,999 | 12 (5.8%) |
| $38,000-$44,999 | 6 (2.9%) |
| $45,000-$54,999 | 7 (3.4%) |
| $55,000-$64,999 | 7 (3.4%) |
| $65,000-$74,999 | 11 (5.2%) |
| $75,000-$99,999 | 21 (10.1%) |
| $100,000 or more | 77 (37.0%) |
| Unknown | 57 (27.4%) |
| **Level of education** | |
| < Highschool Diploma | 87 (41.8%) |
| Highschool Diploma or Equivalent | 35 (16.8%) |
| Associates Degree | 20 (9.6%) |
| Bachelors Degree | 41 (19.8%) |
| Masters Degree | 21 (10.1%) |
| Doctoral Degree | 4 (1.9%) |

**Of note, the race does not correspond to the total number of patients as some patients with mixed races were included in the analysis.*

| | |
|---|---|
| **Slope** | 0.84<br>95% CI = [0.78, 0.89] |
| **Intercept** | -0.3 mm<br>95% CI = [0.1, 0.4]* |
| **Bias at 0.0 mm** | -0.3 mm<br>95% CI = [0.1, 0.5]* |
| **Bias at 3.0 mm** | -7.0%<br>95% CI = [-11.5 -3.5] |
| **Bias at 5.0 mm** | -11.2%<br>95% CI = [-15.6, -7.1] |
| **Bias at 7.0 mm** | -13.0%<br>95% CI = [-18.2, -8.3] |
| **Bias at 9.0 mm** | -14.1%<br>95% CI = [-19.8, -8.8] |

*Of note, the difference between the two 95% CI is due to the fact that the bootstrap is used for bias CI calculation, whereas for the intercept and slope it is the standard CI calculation linked to Passing-Bablok regression that is used.

*Overjet – 3D Monitoring*

A total of 263 patients rendering 292 results were included in the analysis. One patient could render multiple results corresponding to both central incisor couples.

| Characteristic | # (%) |
|---|---|
| **Gender** | |
| Male | 83 (31.6%) |
| Female | 180 (68.4%) |
| **Age group** | |
| [6; 12] years of age | 48 (18.3%) |
| ]12; 22[ years of age | 80 (30.4%) |
| ≥ 22 years of age | 135 (51.3%) |
| **Race*** | |
| American Indian or Alaska Native | 10 (3.8%) |
| Asian | 9 (3.4%) |
| Black or African American | 29 (11.0%) |
| Native Hawaiian or Other Pacific Islander | 0 (0.0%) |
| White | 202 (77.2%) |
| Unknown race | 17 (6.5%) |
| **Ethnicity** | |
| Spanish origin | 36 (13.7%) |
| Not Hispanic or Latino | 227 (86.3%) |
| **Income of the household (annual)** | |
| Less than $19,999 | 11 (4.2%) |
| $20,000-$37,999 | 15 (5.7%) |
| $38,000-$44,999 | 7 (2.7%) |
| $45,000-$54,999 | 7 (2.7%) |
| $55,000-$64,999 | 12 (4.5%) |
| $65,000-$74,999 | 17 (6.5%) |
| $75,000-$99,999 | 25 (9.5%) |
| $100,000 or more | 90 (34.2%) |
| Unknown | 79 (30.0%) |
| **Level of education** | |
| < Highschool Diploma | 100 (38.0%) |
| Highschool Diploma or Equivalent | 45 (17.1%) |
| Associates Degree | 28 (10.6%) |
| Bachelors Degree | 61 (23.2%) |
| Masters Degree | 24 (9.2%) |
| Doctoral Degree | 5 (1.9%) |

**Of note, the race does not correspond to the total number of patients as some patients with mixed races were included in the analysis.*

| | |
|---|---|
| **Slope** | 1.03<br>[1.01, 1.05] |
| **Intercept** | 0.14 mm<br>[0.09, 0.19]* |
| **Bias at 0.00 mm** | 0.14 mm<br>[0.07, 0.23]* |
| **Bias at 3.00 mm** | 7.2%<br>[6.0, 8.9] |
| **Bias at 5.00 mm** | 5.4%<br>[4.5, 6.7] |
| **Bias at 7.00 mm** | 4.7%<br>[3.7, 6.0] |
| **Bias at 9.00 mm** | 4.3%<br>[3.2, 5.6] |

*Of note, the difference between the two 95% CI is due to the fact that the bootstrap is used for bias CI calculation, whereas for the intercept and slope it is the standard CI calculation linked to Passing-Bablok regression that is used.

*Archwire and auxiliaries study*

DentalMonitoring evaluated the passive archwire and auxiliaries indication using 3D Models acquired with intraoral scanners as input data to the Reference Method. The study was performed using data collected prospectively. The study involved six sites located in the United States: five sites for patient enrollment and one site for generation of the Reference Method results.

The Reference Method results were generated by performing a best fit on the acquired 3D Models. The best fit was performed per arch and per patient between the 3D Models acquired at two different timepoints. The best fits were done using a CAD/CAM software.

Data was collected in order to qualify the patient demographics.

*Passive archwire and auxiliaries – 2D Monitoring*

| Characteristic | # (%) |
|---|---|
| **Gender** | |
| Female | 172 (63%) |
| Male | 101 (37%) |
| **Age group** | |
| [6; 12] years of age | 24 (9%) |
| ]12; 22[ years of age | 197 (72%) |
| ≥ 22 years of age | 52 (19%) |
| **Race*** | |
| American Indian or Alaska Native | 8 (3%) |
| Asian | 11 (4%) |
| Black or African American | 48 (18%) |
| Native Hawaiian or Other Pacific Islander | 1 (0.3%) |
| White | 190 (70%) |
| Refused to disclose | 31 (11%) |
| **Ethnicity** | |
| Spanish origin | 64 23%) |
| Not Hispanic or Latino | 209 (77%) |
| **Income of the household (annual)** | |
| Less than $19,999 | 16 (6%) |
| $20,000-$37,999 | 17 (6%) |
| $38,000-$44,999 | 16 (6%) |
| $45,000-$54,999 | 16 (6%) |
| $55,000-$64,999 | 13 (5%) |
| $65,000-$74,999 | 10 (4%) |
| $75,000-$99,999 | 31 (11%) |
| $100,000 or more | 76 (28%) |
| Refused to disclose | 78 (28%) |
| **Level of education** | |
| < Highschool Diploma | 175 (64%) |
| Highschool Diploma or Equivalent | 31 (11%) |
| Associates Degree | 18 (7%) |
| Bachelors Degree | 32 (12%) |
| Masters Degree | 11 (4%) |
| Doctoral Degree | 5 (2%) |
| Not collected | 1 (0%) |

**Of note, the race does not correspond to the total number of patients as some patients with mixed races were included in the analysis.*

| | | Reference Method | | |
|---|---|---|---|---|
| | | Passive | Active | TOTAL |
| Candidate Method | Positive class: Passive | 357 | 63 | 420 |
| | Negative class: Active | 43 | 267 | 310 |
| | TOTAL | 400 | 330 | 730 |

| | Result | 95% CI Lower Bound | 95% CI Upper Bound |
|---|---|---|---|
| Sensitivity | 89.0% | 84.9% | 92.1% |
| Specificity | 80.4% | 75.1% | 84.8% |

| Characteristic | # (%) |
|---|---|
| **Gender** | |
| Female | 166 (62%) |
| Male | 103 (38%) |
| **Age group** | |
| [6; 12] years of age | 27 (10%) |
| ]12; 22[ years of age | 196 (73%) |
| ≥ 22 years of age | 46 (17%) |
| **Race*** | |
| American Indian or Alaska Native | 9 (3%) |
| Asian | 11 (4%) |
| Black or African American | 43 (16%) |
| Native Hawaiian or Other Pacific Islander | 1 (0.4%) |
| White | 189 (70%) |
| Refused to disclose | 31 (12%) |
| **Ethnicity** | |
| Spanish origin | 64 (24%) |
| Not Hispanic or Latino | 209 (76%) |
| **Income of the household (annual)** | |
| Less than $19,999 | 13 (5%) |
| $20,000-$37,999 | 14 (5%) |
| $38,000-$44,999 | 12 (4%) |
| $45,000-$54,999 | 13 (5%) |
| $55,000-$64,999 | 15 (6%) |
| $65,000-$74,999 | 9 (3%) |
| $75,000-$99,999 | 34 (13%) |
| $100,000 or more | 81 (30%) |
| Refused to disclose | 78 (29%) |
| **Level of education** | |
| < Highschool Diploma | 174 (65%) |
| Highschool Diploma or Equivalent | 28 (10%) |
| Associates Degree | 18 (7%) |
| Bachelors Degree | 30 (12%) |
| Masters Degree | 12 (4%) |
| Doctoral Degree | 4 (1%) |
| Not collected | 3 (1%) |

**Of note, the race does not correspond to the total number of patients as some patients with mixed races were included in the analysis.*

| | | Reference Method | | |
|---|---|---|---|---|
| | | Passive | Active | TOTAL |
| Candidate Method | Positive class: Passive | 361 | 48 | 409 |
| | Negative class: Active | 39 | 282 | 321 |
| | TOTAL | 400 | 330 | 730 |

| | Result | 95% CI Lower Bound | 95% CI Upper Bound |
|---|---|---|---|
| Sensitivity | 90.4% | 86.7% | 93.2% |
| Specificity | 85.5% | 80.8% | 89.2% |

*Updated 3D Model study*

DentalMonitoring evaluated the Updated 3D Model indication using 3D Models acquired with intraoral scanners as the Reference Method. For each case, they compared the 3D Model generated by Dental Monitoring to the baseline 3D Model using a best fit between the two 3D objects. Each best fit renders a deviation value and this value is then used to quantify the absolute difference between the two 3D objects, which was used to calculate the mean absolute error (MAE). The study was performed using data collected prospectively. The study involved seven sites located in the United States: six sites for patient enrollment and one site for generation of the study results.

The study results were generated by performing a best fit between the acquired 3D Models and the 3D Model generated by DentalMonitoring, *i.e.* Updated 3D Model. The best fit was performed per arch and per patient. The best fits were done using a CAD/CAM software.

Data was collected in order to qualify the patient demographics.

| Characteristic | # (%) |
|---|---|
| **Gender** | |
| Female | 80 (32.0%) |
| Male | 170 (68.0%) |
| **Age group** | |
| ]12; 22[ years of age | 114 (45.6%) |
| ≥ 22 years of age | 136 (54.4%) |
| **Race*** | |
| American Indian or Alaska Native | 14 (5.6%) |
| Asian | 8 (3.2%) |
| Black or African American | 12 (4.8%) |
| Native Hawaiian or Other Pacific Islander | 0 (0.0%) |
| White | 221 (88.4%) |
| Refused to disclose | 4 (1.6%) |
| **Ethnicity** | |
| Spanish origin | 22 (8.8%) |
| Not Hispanic or Latino | 226 (90.4%) |
| Unknown | 2 (0.8%) |
| **Income of the household (annual)** | |
| Less than $19,999 | 9 (3.6%) |

| | |
|---|---|
| $20,000-$37,999 | 18 (7.2%) |
| $38,000-$44,999 | 7 (2.8%) |
| $45,000-$54,999 | 12 (4.8%) |
| $55,000-$64,999 | 12 (4.8%) |
| $65,000-$74,999 | 13 (5.2%) |
| $75,000-$99,999 | 32 (12.8%) |
| $100,000 or more | 81 (32.4%) |
| Refused to disclose | 66 (26.4%) |
| **Level of education** | |
| < Highschool Diploma | 106 (42.1%) |
| Highschool Diploma or Equivalent | 34 (13.5%) |
| Associates Degree | 29 (11.6%) |
| Bachelors Degree | 53 (21.0%) |
| Masters Degree | 24 (9.5%) |
| Doctoral Degree | 5 (2.0%) |
| Unknown | 1 (0.4%) |

**Of note, the race does not correspond to the total number of patients as some patients with mixed races were included in the analysis.*

| # of patients | # of results | Mean Absolute Error (MAE) | 95% CI |
|---|---|---|---|
| 250 | 536 | 0.10 | [0.093; 0.103] |

*Human Factors Testing*

A Human factors validation testing was performed to demonstrate the usability of the device. Considering DentalMonitoring has two external user-facing interfaces, *i.e.* the Dashboard and the DM App, one study was performed for each of these interfaces.

Dashboard study

The Dashboard study enrolled two user groups:

- doctors; and
- practice employees.

Doctors represented 17 participants while practice employees represented 16 participants.

Testing took place in the United States in three cities, each located in different states.

The testing shows that the Dashboard can be used safely and effectively by the user population. Most of the users used the device properly and there is no significative difference between the different groups of population. Even if some use errors and use difficulties were observed, they cannot cause any harm to the users based on the performed analysis of the root cause. Furthermore, in the Dashboard, no tasks are considered as critical.

DM App study

The DM App study was divided into two parts: validation of the healthcare professional-facing interface

which offers some of the features of the Dashboard, and validation of the patient-facing interface.

The DM App healthcare professional-facing interface study enrolled one user group constituted of doctors and practice employees. A total of 17 doctors along with 16 practice employees composed a testing group of 33 participants.

Testing took place in the United States in three cities, each located in different states.

The testing shows that the DM App healthcare professional-facing interface can be used safely and effectively by the user population. Most of the users used the device properly and there is no significative difference between the different groups of population. Furthermore, even if some use errors and use difficulties were observed, they cannot cause any harm to the users based on the performed analysis of the root cause.

The DM App patient-facing interface study enrolled five user groups:

- adults 22 years of age or older;
- adolescents between 13 and 21 years old;
- children: pairs of pediatric patients (6 to 12 years of age) and lay caregivers (22 years of age or older);
- adults with disabilities: pairs of adult patients with disabilities who cannot independently use the product (22 years of age or older) and lay caregivers (22 years of age or older); and
- healthcare professionals (includes doctors and practice employees).

| **Population group** | adults | adolescents | children | adults with disabilities | healthcare professionals |
|---|---|---|---|---|---|
| **# of participants** | 16 | 15 | 15 | 17 | 17 |

Testing took place in the United States in five cities, each located in different states. This study included use of the DM Cheek Retractor and DM ScanBox which are mandatory hardware products to be used with the DM App in order to appropriately acquire Scans.

The testing shows that the DM ScanBox, the DM Cheek Retractor and the DM App, can be used safely and effectively by the user population. Most of the users used the device properly and there is no significative difference between the different groups of population. Furthermore, some use errors and use difficulties were observed; however, they are not expected to cause any harm to the users based on an analysis of the root cause that was conducted. Users were able to execute the relevant tasks directly or in workarounds within the patient profiles. The task errors identified were found to be non-critical and the testing was able to demonstrate that the device can be adequately used by the health care professional and patient according to the instructions for use.

## LABELING

Labeling has been included. It comprises a user manual dedicated to healthcare professionals on one hand and a user manual dedicated to patients on the other hand.

Labeling also includes the two distinct labels embedded in the Dashboard, and in the DM App.

## RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of and the measures necessary to mitigate these risks.

| Identified Risk | Potential Mitigation Measure |
|---|---|
| Adverse tissue reaction | Biocompatibility evaluation |
| Use error/ improper device use leading to incorrect oral health information conveyed to healthcare professional | Labeling<br>Usability testing |
| Software malfunction leading to inaccurate patient monitoring and diagnosis | Software verification, validation, and hazard analysis, |
| Software failure to identify or monitor the correct oral health condition leading to delayed treatment | Clinical validation<br>Software verification, validation, and hazard analysis |
| Device failure to adequately capture image leading to incorrect identification or monitoring of oral health condition | Non-clinical performance testing<br>Technological specifications |

**SPECIAL CONTROLS**

In combination with the general controls of the FD&C Act, the Dental Image Analyzer is subject to the following special controls:

(1) The patient-contacting components of the device must be demonstrated to be biocompatible.
(2) Non-clinical performance testing data must demonstrate that the device performs as intended under anticipated conditions of use and must include full specifications of the hardware requirements and testing to demonstrate the specified hardware ensures adequate data for validated and accurate measurements;
(3) Clinical performance data must demonstrate the accuracy and precision of the diagnostic and monitoring device algorithms to perform as intended under anticipated conditions of use.
(4) Usability testing must demonstrate that the user can correctly use the device, based solely on reading the directions for use.
(5) Software verification, validation, and hazard analysis must be performed.
(6) Labeling must include:
    (i) Information on the patient population for which the device has been demonstrated to be effective.
    (ii) Information on how the device operates during the typical course of treatment
    (iii) A detailed summary of the device technical parameters, including compatible operating systems, hardware, and/or accessories.
    (iv) Instructions for cleaning of any reusable components.
    (v) Warning that the device is not intended to be used independently for diagnosis and that the device does not replace clinical decision making.
(7) Patient labeling must be provided and must include:
    (i) Relevant contraindications, warnings, precautions, adverse effects/complications, and when to seek help from a dental healthcare professional.
    (ii) Information on how the device operates during the typical course of treatment.
    (iii) A detailed summary of the device technical parameters, including compatible operating systems, hardware, and/or accessories.
    (iv) Information on the patient population for which there is clinical evidence of effectiveness.
    (v) Instructions for cleaning of any reusable components.

## BENEFIT-RISK DETERMINATION

The risks of the device are based on data collected in a clinical studies described above. Both the clinical and usability risks of the device have been evaluated and use of the device itself presents no significant direct risks to the user. The key clinical risk of this proposed device are the inability to identify or monitor the correct oral health condition leading to delayed treatment. The risks were quantified by sensitivity and specificity in the clinical study, which demonstrated the device's function. The risk of the proposed device is low.

The probable benefits of the device are also based data collected in a clinical studies as described above. This device can be a benefit to the clinician to monitor orthodontic progress between scheduled appointments and facilitate additional interaction between patient and clinician, as needed. Additionally, the device can provide benefit by specifically identifying potential clinical scenarios and areas of concern that would require further evaluation/intervention. The device is not intended to replace regularly scheduled appointments and would be considered low risk, as it ultimately facilitates more interaction between the patient and clinician during treatment.

## PATIENT PERSPECTIVES

This submission did not include specific information on patient perspectives for this device.

## BENEFIT/RISK CONCLUSION

In conclusion, given the available information above, for the following indication statement:

DentalMonitoring is a medical device software using image processing algorithms to analyze pictures of the oral cavity (hereinafter Scans). Scans are taken using the DM App, a smartphone, and the manufacturer's proprietary hardware products. Scans are taken by the patient, a non-healthcare professional, or a healthcare professional. The Scan is taken in healthcare facilities, such as a dental practice, or in a non-healthcare environment, such as the patient's own home. For some clinical parameters, DentalMonitoring requires a 3D Model.
The product is designed to assist healthcare professionals in remotely monitoring orthodontic treatments and treatment progress. The results of DentalMonitoring are intended to be used as an aid in diagnosis and monitoring, not on a stand-alone basis for clinical decision-making.
DentalMonitoring is indicated for use for patients over the age of 6 and reports results solely on permanent teeth.

DentalMonitoring can monitor the following clinical parameters:

- oral hygiene: dental plaque / food residue;
- soft tissue statement: gingival recession, black triangle;
- dental statement: closure of extraction space, tooth wear;
- alignment: closure of all anterior spaces; and
- dental occlusion:
    - in 2D Monitoring: midline deviation, overbite/open bite, overjet
    - in 3D Monitoring: canine class, midline deviation, overbite/open bite, overjet

Additionally, the following clinical parameters specific to orthodontic treatment types or phases can be monitored using DentalMonitoring:

- for aligner treatments: tracking (seat/unseat), attachment loss, button loss;
- for braces: bracket debonding, tie loss, self-ligating clips, passive archwire and auxiliaries; and
- for thermoformed retainers: tracking (seat/unseat).

Based on an initial 3D Model provided by a healthcare professional, DentalMonitoring can also provide healthcare professionals with 3D Models representative of the patient's dentition and treatment progress. This device is a prescription device and is not intended for over-the-counter use.

The probable benefits outweigh the probable risks for the DentalMonitoring. The device provides benefits and the risks can be mitigated by the use of general and the identified special controls.

**CONCLUSION**

The De Novo for the DentalMonitoring is granted and the device is classified as follows:

Product Code: SBC

Device Type: Dental Image Analyzer

Regulation Number: 21 CFR 872.1770

Class: Class II