APPENDIX B

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Supplemental Data Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE — FOOD AND DRUG ADMINISTRATION

SUPPLEMENTAL DATA SHEET

FORM APPROVED: OMB NO. 0910-0138
EXPIRATION DATE: January 1, 2000
(See OMB Statement on Page 2)

1. GENERIC TYPE OF DEVICE
Data acquisition devices for CAD-CAM dental restoration

2. ADVISORY PANEL
Dental Devices Panel

3. IS DEVICE AN IMPLANT?
☐ Yes ☒ No

4. INDICATIONS FOR USE PRESCRIBED, RECOMMENDED, OR SUGGESTED IN THE DEVICE'S LABELING THAT WERE CONSIDERED BY THE ADVISORY
The types of devices included in this reclassification petition are used to record the topographical characteristics of teeth, dental impressions, or dental molds by analog or digital methods for use in the computer-aided design and milling of dental restorative prosthetic devices. These systems may consist of a camera, scanner or equivalent type of sensor, and a computer with software.

5. IDENTIFICATION OF ANY RISKS TO HEALTH PRESENTED BY DEVICE

General **Intra-oral camera:** Cross-contamination from dental camera if not cleaned sufficiently between patients, electrical safety and electromagnetic compatibility risks. Risks are to patient and operator.

Laser Scanner: Risks of exposure to Class II laser radiation if safety interlocks fail, electrical safety and electromagnetic compatibility risks. Risks are to operator only.

Both types: Risk to patient of improper restoration design or fit. Risk is mitigated because design, manufacture and fitting of restoration is done under the supervision of a trained dentist or dental technician.

Specific Hazards to Health	Characteristics or Features of Device Associated with Hazard
a. Cross-contamination	a. Adequate cleaning and disinfection instructions can be provided
b. Electrical safety and electromagnetic compatibility	b. AC powered. Can be manufactured to UL or IEC standards
c. Laser	c. Class II diode laser. Safety interlocks reduce exposure levels to Class I.
d. Improper data	d. Design, manufacture and fit of restoration done under control of trained personnel.

6. RECOMMENDED ADVISORY PANEL CLASSIFICATION AND PRIORITY
Class I, exempt from 510(k) premarket notification

Classification _____ Priority (Class II or III Only) _____

7. IF DEVICE IS AN IMPLANT, OR IS LIFE-SUSTAINING OR LIFE-SUPPORTING AND HAS BEEN CLASSIFIED IN A CATEGORY OTHER THAN CLASS III, EXPLAIN FULLY, THE REASONS FOR THE LOWER CLASSIFICATION WITH SUPPORTING DOCUMENTATION AND DATA
Not applicable

8. SUMMARY OF INFORMATION, INCLUDING CLINICAL EXPERIENCE OR JUDGMENT, UPON WHICH CLASSIFICATION RECOMMENDATION IS BASED
See Section 9 and Appendix E of reclassification petition.

9. IDENTIFICATION OF ANY NEEDED RESTRICTIONS ON THE USE OF THE DEVICE
The device should be available by prescription only, sold by or on the order of a licensed dentist or dental technician.

10. IF DEVICE IS IN CLASS I, RECOMMEND WHETHER FDA SHOULD EXEMPT IT FROM

Justification / Comments

☐ a. Registration / Device Listing

☒ b. Premarket Notification — Risks associated with this type of device are low, well-understood and similar to other Class I dental products exempt from premarket notification. Device used under control of trained dentist or dental technician.

☐ c. Records and Reports

☐ d. Good Manufacturing Practice

11. EXISTING STANDARDS APPLICABLE TO THE DEVICE, DEVICE SUBASSEMBLIES *(Components)* OR DEVICE MATERIALS *(Parts and Accessories)*

IEC 60601-1 (Electrical safety)

IEC 609601-1-2 (Electromagnetic compatibility)

UL 2601 (Electrical safety)

21 CFR Subchapter J, section 1040 (Laser safety, for devices with laser scanners)

12. COMPLETE THIS FORM PURSUANT TO 21 CFR PART 860 AND SUBMIT TO:

Food and Drug Administration
Center for Devices and Radiological Health
Office of Health and Industry Programs (HFZ-215)
1350 Piccard Drive
Rockville, MD 20850

OMB STATEMENT

Public reporting burden for this collection of information is estimated to average 1-2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

DHHS Reports Clearance Officer, Paperwork Reduction Project (0910-0138)
Hubert H. Humphrey Building, Room 531-H
200 Independence Avenue, S.W.
Washington, DC 20201

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