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**Class II 510(k) Exemption Petition -- "T1Pal.com"**

This letter is our petition for an exemption for a new "software as a Medical Device (SaMD)", a web site, branded "T1Pal.com" that we assert aligns with FDA classification of a Class II device requiring no PMN.

As provided by FDAMA, FDA exempted through a FEDERAL REGISTER (FR) notice, 62 class II device types from premarket notification (section 510(k)) requirements on January 21, 1998 (63 FR 3142). Within the document for "Procedures for Class II Device Exemption from Premarket Notification, Guidance for Industry and CDRH staff...", the FDA, upon its own initiative or upon a petition of an interested person, may exempt a class II device from premarket notification requirements under section 510(m)(2).

Referring to the FDA's web site *https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device*", device classification depends on the 1) **intended use** of the device and 2) upon **indications for use**."

1. T1Pal.com has no "***Indications*** for use"
2. "***Intended* *Use***" cases for T1Pal.com together with additional requirements are listed in a table 1 below.
3. Additional "System Requirements" of the T1Pal system and are also listed in table 2 below so as to previously discussed address FDA "special controls, validations, and quality controls."

"Medical Data Networks LLC" EIN: 85-1505127 is the developer and operator of the T1Pal.com software. As such, the "manufacturer's" Quality Management System is well documented and operational, and able to provide FDA and others "...assurance of safety and effectiveness...such as current good manufacturing practice requirements, provide..." We would be pleased to review the details of our QMS system at your pleasure.

Altogether, the three Intended Use cases, and the Additional System Requirements below, together with the present Quality Management system, T1Pal should meet FDA rules for clearance -- using the De Novo pathway, and the T1Pal realization of "Special Controls" enumerated in meeting minutes Q141084/S002 dated 1/27/2015.

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| **Table 1 -- List of All Intended Use Cases** | |
| **Requirement ID (in QMS)** | **Intended Use Text** |
| REQ\_1010 -- Secondary Display | It is an intended use for T1Pal to receive data from one or more medical devices and provide a secondary display of the data. |
| REQ\_1020 -- Remote Access | It is an intended use that authorized "followers" will have remote access to a secondary display of the same data. |
| REQ\_1030 -- Technical Support | It is intended that the display of secondary data will be used to provide "Technical Support."  "Technical Support" in this  case is limited to providing artifacts, displays, or *documentation* that hasten:   1. device warranty claims, 2. guidance on replacement of devices or consumables, and 3. acts that remedy impairments to data communications. |
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| **Taable 2 -- Additional T1Pal System Requirements** | |
| **Requirement ID (in QMS)** | **Requirement Text** |
| REQ\_2010 -- Data Privacy and Modification Protections | The T1Pal is intended to be HIPPA compliant with respect to privacy and access to data. |
| REQ\_2020 -- Protection against modification of data. | The T1Pal is intended to protect against modification of data provided for secondary display. |
| REQ\_2030 -- T1Pal Labelling | The T1Pal software shall provide clear and unambiguous labelling that describes both intended use, and warnings against all other uses. |
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As a note to the reader, T1Pal.com was developed and is owned by Medical Data Networks LLC and includes a significant open-sourced component copy of Nightscout software, previously discussed in FDA meetings. Importantly, T1Pal.com adds requisite QMS controls and validation of specific Intended Use labelling, and other privacy and security features outlined above.

Petitioner's Request Summary

1. Leveraging past correspondence (ref. Meeting Minutes Q141084/S002, 2/27/2015) regarding Nightscout software, we are relying on an update that similarly classifies T1Pal.com as a Class II software medical device that requires no 510(k) submission, and no 513(g) request to commence marketing of the T1Pal product.
2. Also included in this petition is the classification of the owner of "T1Pal" web site (Medical Data Networks LLC) EIN: 85-1505127 as a “small business” and therefore eligible for "substantial reduction in user fees."

Very Truly Yours

Ben West, CEO

Medical Data Networks LLC