Vivos Therapeutics, Inc.

*Vivos is registered, with the FDA, as a Specification Developer

Vivos System Appliances:

1. **Vivos mRNA** *(Mandibular Repositioning Nightime Appliance)*: **FDA CLEARED as a Class 2 appliance**; cleared for the treatment of adult patients diagnosed with mild to moderate sleep apnea, snoring and sleep disordered breathing.

    a. E0486 - CPT Medical Billing Code-Requires a diagnosis of OSA (from an MD) and a Sleep Study for Pre-auth and Billing. Never a guarantee of payment.

2. **Vivos DNA** *(Daytime Nightime Appliance)*: **FDA REGISTERED as a Class 1 appliance** for palatal expansion / Orthodontics

    a. 21299 - CPT Medical Billing Code – this is an unspecified medical CPT code that will require a (LMN) Letter of Medical Necessity from Dentist for pre-authorization and billing. Please include your Lab RX for supportive documentation. Never a guarantee of payment.

3. **Vivos Guide Series** (VStarter, VGrow, VWay): **FDA REGISTERED as Class 1 appliances** for teeth straightening/ Orthodontics in Children

    a. 21299 - CPT Medical Billing Code- this is an unspecified medical CPT code that will require a (LMN) Letter of Medical Necessity from the Dentist for pre-authorization and billing. Please include your Lab RX for supportive documentation. Never a guarantee of payment.

Regulatory Information: The FDA never approves Class I and Class II medical devices. The FDA will only approve drugs. The FDA will only **clear** medical devices with the submission of a 510(k) and clinical data where a specification developer will request additional indications of use. The FDA has Cleared the mRNA for the indications of use as listed above as a Class II device.

IRB Standford University Approved Protocol for mRNA Clinical Trials. This trial is in the beginning stages and we estimate a start date of Q1 2021.

Approved WIRB Clinical Trails are ongoing for the Guide Series and DNA for children. These trials are listed confidential on clinicaltrials.gov

*Vivos currently has a *PENDING 510(K) for the DNA* right now awaiting FDA review so that we may eventually have additional indications of use added to the Vivos DNA for adults.

*Vivos is also working on a new 510k for a device called the mmRNA (Modified Mandibular Repositioning Nightime Appliance) This device is modified with a fixed mechanical hinge where the mRNA has a flange. This device will meet the criteria for E0486 under Medicare Guidelines and are plan is to have the mmRNA added to the Medicare Approved list of devices (PDAC). We estimate this device to be out in the market Q1 or early Q2.of 2021.