K961805

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SECTION VI

510(k) SUMMARY

Tomey DTL Electrode

Common/Classification Name: Electrode Corneal, 21 CFR 886.1220

Applicant:

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A. LEGALLY MARKETED PREDICATE DEVICES

The **Tomey DTL Electrode** is substantially equivalent in design and function to the DTL Electrode as manufactured by Sauquoit Industries, Inc., Scranton, PA (as cleared in K844409), the Gold Foil ERG Electrodes as manufactured by Cadwell Laboratories, Inc., Kennewick, WA (as cleared in K820254), and the ERG-JET Electrode as manufactured by Life Tech, Houston, TX (as cleared in K823767).

The **Tomey DTL Electrode** is also similar to the ERG electrode that was included with the **Tomey PE-400/PS-400 Portable ERG** system under K932571.

B. DEVICE DESCRIPTION

Tomey DTL Electrode consists of soft silver impregnated nylon fiber threads that are normally placed under the lower eye lid. The electrodes are constructed with 3 to 10 individual fibers between 5 and 20 microns in diameter. The fibers are stabilized at both ends with adhesive attachments. A thin wire is connected to an adaptor cable that permits the electrodes to be used with various ERG Recording systems including the Tomey PE-400/PS-400.

C. INTENDED USE

The **Tomey DTL Electrode** is intended for use in the measurement and recording of ERG signals from the ocular surfaces of the eye. These measurements are only to be performed by licensed practitioners and trained technicians within a medical environment.

There are no differences with respect to the predicate devices for indications for use, or target population.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **Tomey Corporation** device has the *same* intended use and target population as the predicate devices, and has *equivalent effectiveness* for its intended use.

E. NON-CLINICAL TESTING

This section summarizes the performance testing that **Tomey Corporation** carried out on the **Tomey DTL Electrode**. This testing addressed the following issues:

1. Elution testing

The **Tomey DTL Electrode** passed the Elution test performed according to the requirements of the Ministry of Health and Welfare in Japan.

2. Rabbit Eye irritation testing

An eye irritation test was performed by Juridical Foundation, Japan Food Research Laboratory which indicates that the **Tomey DTL Electrode** does not cause irritation to the eye when used according to prescribed instructions.

3. Sterilization

The **Tomey DTL Electrode** is supplied to the user in a factory sealed package and is intended to be disinfected by the end user employing procedures recommended in the product labeling.

4. Biocompatibility

The **Tomey DTL Electrode** is for short term ERG recording purposes. Extensive use by many investigators, including Dawson, Prager and Lachapelle, has not revealed any biocompatibility problems with this type of an electrode. Eye Irritation studies performed by **Tomey**, also indicate that short term biocompatibility is not a problem for the **Tomey DTL Electrode**.

5. Other Safety and Compatibility

The **Tomey DTL Electrode**, by means of adaptor cables, is compatible with commercially available ERG recording systems that employ protected electrode leads.

The **Tomey DTL Electrode** is unable to be mistakenly connected to an a/c or d/c power source.

F. CONCLUSIONS

Tomey Corporation has demonstrated that its evaluation of the **Tomey DTL Electrode** and its review of the literature shows equivalent safety and effectiveness with respect to performance, biocompatibility issues, comfort and corneal surface damage, although no specific claim for these attributes is being made.