

AUG 30 1999

Special 510(k) Premarket Notification  
Organon Teknika Corporation  
TOF-Watch SX

K992598

**510(k) Summary**

- (a)(1) **The submitter's name, address, telephone number, a contact person, and the date the summary was prepared;**

**Submitter's Name: Organon Teknika Corporation**

**Submitter's Address: 100 Akzo Avenue  
Durham, North Carolina 27712**

**Submitter's Telephone: (919) 620-2288**

**Submitter's Contact: Rebecca A. Rivas**

**Date 510(k) Summary Prepared: 7/28/99**

- (a)(2) **The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known;**

**Trade or Proprietary Name: TOF-Watch SX**

**Common or Usual Name: TOF-Watch SX**

**Classification Name: Electrical Nerve Stimulator**

- (a)(3) **An identification of the legally marketed device to which the submitter claims substantial equivalence;**

**Device Equivalent to: TOF-Watch**

- (a)(4) **A description of the device.**

The TOF-Watch SX device is a neuromuscular transmission monitor capable of estimating the degree of neuromuscular block in anesthetized patients. It can be used as an objective monitor using accelerometry for measuring the muscle contraction following a stimulation of the respective motoneuron, as a peripheral nerve stimulator (without the objective measuring function) for subjective monitoring and as a nerve location device utilizing a needle electrode. The TOF - Watch SX device is packaged individually in a neutral carton box. The complete package contains a TOF-Watch SX, an acceleration transducer, a surface electrode cable and a multilingu manual.

- (a)(5) **A statement of the intended use of the device.**

The TOF-Watch SX device can be used as an objective monitor using accelerometry for measuring the muscle contraction following stimulation of the respective motoneuron, as a peripheral nerve stimulator (without the objective measuring function) for subjective monitoring or as a nerve location device.

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TOF-Watch SX

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(a)(6) A summary of the technological characteristics of the new device in comparison to those of the predicate device.

Comparison of TOF- Watch to TOF Watch SX

Features	TOF-Watch	TOF-Watch SX
<b>Stimulation patterns (monitoring)</b>		
TOF	Yes	Yes
PTC	Yes	Yes
1 Hz	Yes	Yes
0.1 Hz	Yes	Yes
DBS	Yes	Yes(see P button)
TET	Yes	Yes(see P button)
TOF <sup>s</sup> (stimulation with user programmable interval)	No	Yes (1-60 min)
P button(user programmable button)	No	Yes (DBS, TET, OFF)
Stimulation current range	0-60mA, ≤ 5 KΩ	60 mA, ≤ 5 KΩ
Stimulation pulse width	200 μS	200/300 μS
Acceleration transducer	Yes	Yes
Calibration of acceleration transducer sensitivity	1 sequence – auto	2 sequences – auto
Manual sensitivity adj.	No	Yes
User programmable alarms: TOF and TOF <sup>s</sup>	No	2(upper & lower) (limits: #/%TOF, OFF)
User programmable alarms: ON/OFF	No	Yes
Automatic power switch off ( after 2 hours of no operation)	Yes	Yes
Surface temperature sensor	No	Yes (20-41.5°C)
Nerve location – LA	Yes	Yes
Current range	0-6mA, ≤ 5 KΩ	0-6 mA, ≤ 5 KΩ
Pulse width	40 μS	40 μS

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(b)3) **The conclusions drawn that demonstrate that the device is as safe, as effective, and performed as well or better than the legally marketed device identified in (a)(3).**

In summary, the TOF-Watch SX described in this submission is substantially equivalent to the predicate device based on the following similarities:

- Have the same indicated use
- Use the same operating principle
- Incorporate the same basic design
- Incorporate the same materials
- Packaged the same using the same materials and process



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 30 1999

Ms. Rebecca A. Rivas  
Organon Teknika Corp.  
100 Akzo Avenue  
Durham, NC 27712

Re: K992598  
TOF-Watch SX  
Regulatory Class: II (two)  
Product Code: 73 KOI  
Dated: July 30, 1999  
Received: August 3, 1999

Dear Ms. Rivas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

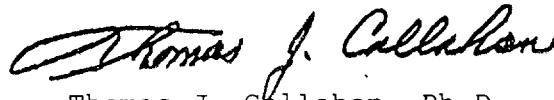
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular,  
Respiratory, and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (If known): k992598

Device Name: TOF-Watch SX

Indications For Use:

The TOF-Watch SX device can be used as an objective monitor using accelerometry for measuring the muscle contraction following stimulation of the respective motoneuron, as a peripheral nerve stimulator (without the objective measuring function) for subjective monitoring or as a nerve location device.

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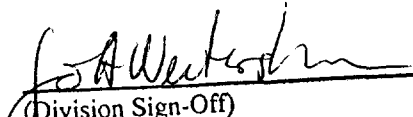
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number k992598