JUN 2 0 2001 K010876

NTI-TSS Inc.
2302 Blue Smoke Trail, Mishawaka, IN 46544 (219) 258-5963

"510(k) Summary"

Submitted by:	NTI-TSS, Inc. James P. Boyd, DDS, CEO
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Contact Person:	Bob Weber Regulatory affairs, NTI-TSS, Inc.
Preparation date:	March 12, 2001
Device name:	NTI Tension Suppression System
Original 510(k) number:	K981546
Product code:	LQZ

Device description:

Nociceptive Trigeminal Inhibition Tension Supression System (NTI-tss):
An intraoral device, 510(k) product K981546.

The NTI-tss is a small intraoral device, which is fitted over the two maxillary central incisors and has a dome shaped protrusion, which extends lingually. The dome is customized by the provider, to act as single point contact at the incisal embrasure of the two mandibular central incisors, thereby preventing posterior or canine tooth contact. The device does not introduce any chemicals or substances into the patient's system.

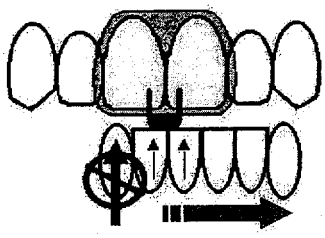
Control Device used to compare to for substantial equivalence:

A full-coverage occlusal splint.
When compared to a placebo (palatal acrylic) a full-coverage occlusal splint reduces migraine frequency by 40%. (Lamey PJ, et al, Migraine: the effect of acrylic appliance design on clinical response, Br Dent J, 180(4):137-40 1996 Feb 24).

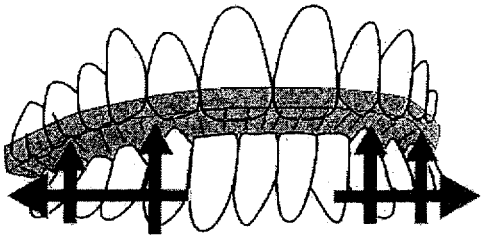
Intended use for the NTI Tension Suppression System:

1. A device to be used in the prophylactic treatment of medically diagnosed migraine pain as well as migraine associated tension-type headaches, through the reduction of neuromuscular activity, and;
2. For the prevention of bruxism and temporomandibular joint syndrome through the reduction of neuromuscular activity

Summary of technological characteristic differences:



NTI Tension Suppression System Device
Anterior midline point stop suppresses muscle contraction intensity of the elevator muscles of the mandible by eliminating posterior and canine contacts, even in excursive movements.



Full coverage occlusal splint
Full coverage occlusal splint supplies posterior and canine contacts in all mandibular movements, thereby allowing for maximal muscle contraction intensity.

Experimental design to compare the NTI-tss and Full-Coverage Splint for the reduction of migraine

A multicentered (4), open-labeled, two parallel groups randomized clinical trial in randomized blocks examined a differential response following an eight-week use of the test device and a control device. This was preceded by a four-week baseline observation assessment.

Patients used a Visual Analog Scale (VAS) to report presence and intensity of head pain three times per day (upon waking in the morning, midday, and at night before bedtime) and percentage of waking time with a headache during the previous 24 hours. Subjects also recorded presence/absence of photophobia, nausea, phonophobia; analgesics taken and dosage; usage of rescue medication (sumatriptan); degree of compliance; and any adverse events.

Inclusion Criteria
Medically diagnosed migraine
-Previously medically screened and diagnosed by a physician as having at least two migraine episodes per month
-Prescribed and using sumatriptan as a rescue medication for their migraine attacks

Pericranial Tenderness
Palpation of the temporalis to confirm tenderness, compared to a control palpation of equal pressure at the mid-hairline on the forehead.

Dental Evaluation
Each subject's dental evaluation required:
- Presence of natural or fixed prosthetic upper and natural lower anterior incisors
- Overbite and overjet within normal limits (requiring no adaptation of the test device)
- Stable dentition: no current orthodontic treatment, teeth fully erupted (excluding third molars)
- No significant periodontal disease or signs and/or symptoms of temporomandibular joint disorder

Baseline Data Collected
Diagnostic opposing study models; measurement of tooth mobility and sensitivity (temperature, pressure, contact by explorer to CEJ); full periodontal charting; anterior periapical x-rays; tooth vitality.

Clinical performance data:

SAFTEY:

Saftey

Following eighth week of NTI-tss use, there was no measurable evidence of:

-tooth movement;
-increased tooth sensitivity;
-extrusion;
-increased periodontal pocket depth;
-widening of the PDLs;
-new pain or discomfort.

There were no reports of dislodgment of the device. In five of the 43 NTI-tss patients, a slight degree of mobility (less than 1mm) was measured at the lower incisors.

As is customary when observing the effect of a prophylaxis method of reducing migraine and tension-type headache, at least one month of use is allowed to lapse before an effect (if any) can be realistically observed.

Full occlusal splint vs. an NTI-tss device at the eighth week of use:

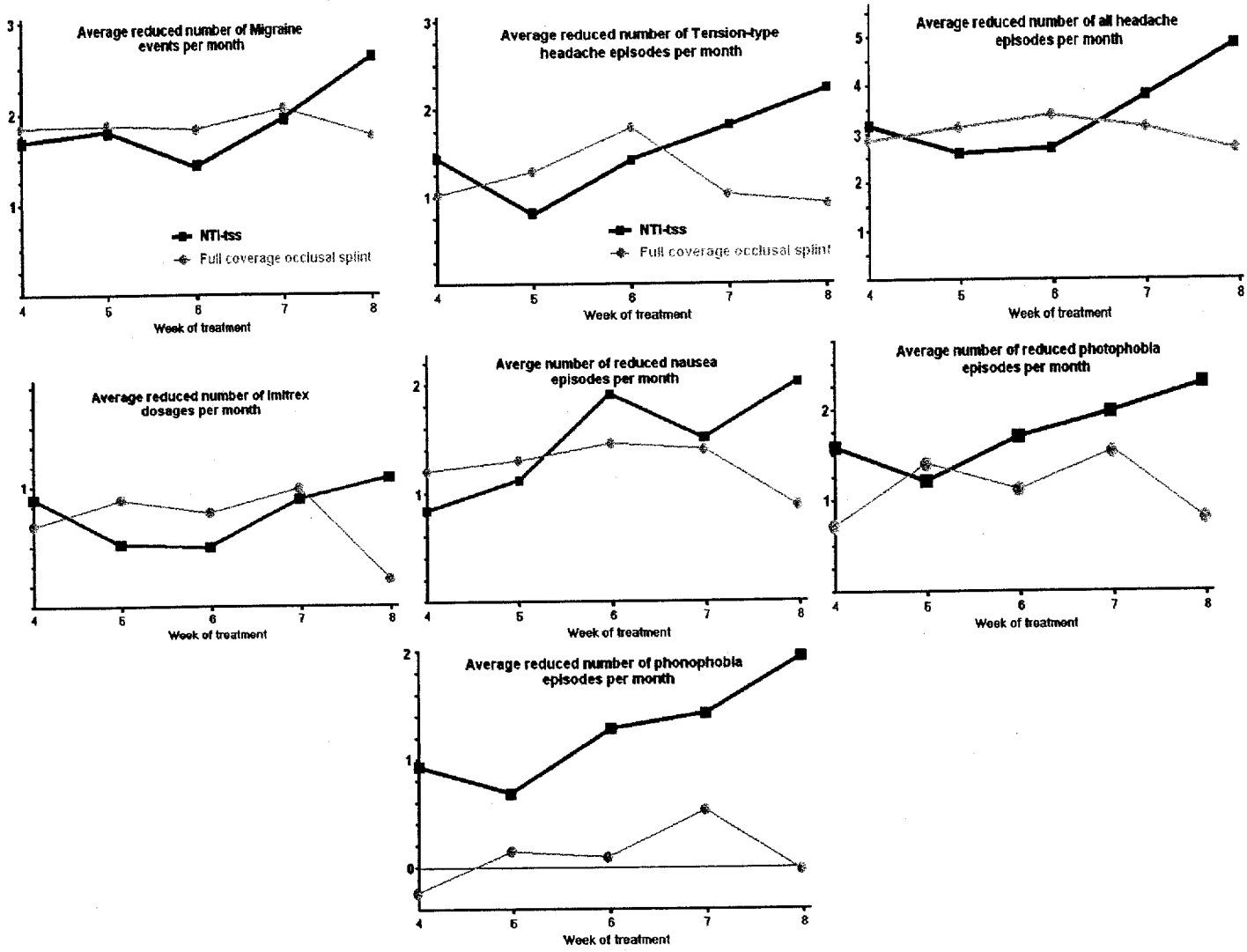
Description	Percentage change of listed symptoms		
	Full Occlusal Splint	NTI-tss	p-value♠
Migraine episodes	-38.1*	-61.9	<.06
Imitrex® use	-17.6	-46.8	<.05
Nausea	-40.4	-78.0	<.01
Phonophobia	+1.6	-68.4	<.02♠
Photophobia	-22.8	-65.6	<.01
Tension-type headache episodes	-15.0	-37.3	<.07
% of waking hours with headpain	-14.6	-35.3	<.02
All headpain episodes	-25.1	-46.9	<.02
Intensity of head pain	-23.7	-36.9	<.08
Analgesic use	-26.0	-20.3	non-sig

♠ P values calculated for *Substantial equivalence* [Blackwelder W.C. Proving the null hypothesis in clinical trials. Controlled Clinical Trials 1982:345-353; Laster LL. The "at least as good as" criterion: sample size requirements. J Dent Res 1995;74, special issue, abstract 299.]

* Consistant with Lamey study which showed a 40% reduction.

♠ Statistically superior

Comparisons of the NTI-tss and full coverage splint during second month of use



Conclusion

There is no significant risk in the treatment of migraine and tension-type headache with the NTI-tss device. The NTI-tss is substantially equivalent or superior to the previously established efficacy of the full-coverage occlusal splint for the reduction of migraine and tension-type headaches and their associated symptoms.

Intended Use for the Device:

1. For the reduction of medically diagnosed migraine and tension-type headache and their associated symptoms, and;
2. For the prevention of bruxism and temporomandibular joint syndrome; through nociceptive suppression of trigeminal neuromuscular activity

James P. Boyd, DDS
CEO, NTI-TSS, Inc.

Comparison of K010876 NTI-tss Device to Predicate devices

	K010876 NTI-tss (new submission)	Custom fabricated full occlusal coverage	K981546 NTI-css
Method of manufacture	**Injection molded**	Laboratory processed	Same
Material	**polycarbonate plastic**	methacrylate acrylic	Same
Risk of exposure	**none**	same	Same
Method of action	**Disruption of activity of pericranial musculature**	same	same
Intended Use	**Prophylactic treatment of medically diagnosed migraine pain; treatment of TM disorders and bruxism**	same	Treatment of TM disorders and bruxism

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 2002

Mr. James P. Boyd
NTI-TSS, Incorporated
2303 Blue Smoke Trail
Mishawaka, Indiana 46544

Re: K010876
Trade/Device Name: NTI Tension Suppression System
Regulation Number: None
Regulation Name: Jaw Repositioning Device
Regulatory Class: Unclassified
Product Code: LQZ
Dated: March 26, 2001
Received: June 6, 2001

Dear Mr. Boyd:

This letter corrects our substantially equivalent letter of June 20, 2001 regarding the Indications for use Statement.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 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 Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K010876

Device Name: NTI Tension Suppression System

Indications for use:

1. A device to be used in the prophylactic treatment of medically diagnosed migraine pain as well as migraine associated tension-type headaches, by reducing their signs and symptoms through reduction of trigeminally innervated muscular activity, and;
2. For the prevention of bruxism and TMJ syndrome through reduction of trigeminally innervated muscular activity

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010876

Prescription Use 1
(Per 21 CFR 801.109)