DE NOVO CLASSIFICATION REQUEST FOR TANGO BELT

REGULATORY INFORMATION

FDA identifies this generic type of device as:

> **Wearable fall injury prevention device**. A wearable fall injury prevention device is intended to detect falls and prevent major fall injuries. Once a fall is detected, the device deploys a protective mechanism to reduce the risk of injury.

NEW REGULATION NUMBER: 21 CFR 890.3780

CLASSIFICATION: Class II

PRODUCT CODE: SEC

BACKGROUND

DEVICE NAME: Tango® Belt (Model SAS-001-01 (XS); Model SAS-001-02 (S); Model SAS-001-03 (M); Model SAS-001-04 (L); Model SAS-001-05 (XL))

SUBMISSION NUMBER: DEN240041

DATE DE NOVO RECEIVED: May 16, 2024

SPONSOR INFORMATION:

Active Protective Technologies, Inc.
580 Virginia Drive, Suite 230
Fort Washington, PA 19034

INDICATIONS FOR USE

The Tango® Belt (Model SAS-001-01 (XS); Model SAS-001-02 (S); Model SAS-001-03 (M); Model SAS-001-04 (L); Model SAS-001-05 (XL)) is indicated as follows:

> The Tango® Belt is indicated as an adjunctive to standard-of-care to reduce the risk of hip fracture or hip dislocation due to falls in older adults at risk of major hip injury due to falls.
> It is for Prescription Use only.

LIMITATIONS

The sale, distribution, and use of the Tango Belt are restricted to prescription use in accordance with 21 CFR 801.109.

The safety and effectiveness of the Tango Belt has not been evaluated in patients under the age of 65 years or those who have a waist circumference outside of 29 – 50 inches (63.5 – 127 cm).

Durability testing has not been completed beyond 3 years.
As with use any medical device, there are potential risks and complications associated with treatment using the Tango Belt. The following adverse reactions may occur:

- Discomfort or soreness
- Shock or anxiety caused by airbag deployment
- Injuries caused by airbag deployment such as bruising or lacerations
- Injuries associated with a fall such as abrasion, contusion, concussion, whiplash, and/or fracture

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

The Tango Belt is a wearable belt designed to protect at risk older adults (65+ years of age) at risk for fall injury by reducing the risk of hip dislocation or hip fracture due to falls. A fall that results in hip dislocation or hip fracture is considered a serious hip-impacting fall.

The Tango Belt can detect a serious hip-impacting fall while in progress using built-in sensors and deploy an airbag to physically protect the hip region from impact forces. When connected to Wi-Fi, the Tango Belt can send automated fall and impact alerts to caregivers and Healthcare Providers (HCPs) while recording motion and event data, which can then be analyzed for usage-based metrics viewable via a mobile or desktop Companion App. The Tango Belt can also send manually activated alerts for help, triggered by pressing a button on the belt buckle, when connected to Wi-Fi. Alerts are sent in the form of SMS texts and emails to alert recipients designated in the mobile or desktop Companion App. The Tango Belt can also detect non-serious hip-impacting or non-hip impacting falls in which the wearer may have incurred a minor injury (i.e., not a major hip injury) and/or may be unable to get up.

The Tango Belt has three components: (1) the Smartbelt, (2) the Companion App, and (3) the Cloud Platform.

1) Smartbelt: The main functionalities of the Smartbelt include gathering motion and use data; detecting a serious hip-impacting fall in progress; deploying the protective airbag;

detecting non-serious hip-impacting or non-hip impacting falls; and triggering alerts, which are sent using AWS Simple Email Service to caregivers and HCPs, i.e., pre-defined contacts. The Smartbelt is solely responsible for clinical function and can perform clinical function even when not connected to Wi-Fi. It is provided in five sizes (XS, S, M, L, and XL).

2) Companion App: The Companion App is used to connect the belt to Wi-Fi networks, set Wi-Fi credentials, adjust local user interface intensity, set contact details for notifications, view usage information, link belts to patients, and enable/disable certain informational notifications (status regarding if the belt is buckled, if the belt is unbuckled, or if the battery is low).
3) Cloud Platform with Desktop Application: The motion and event data recorded and stored within the Smartbelt is periodically (any time the Smartbelt is placed on the charger, and once an hour if it is not on the charger if connected to Wi-Fi) uploaded to the Cloud Platform. The data is then automatically processed by the cloud-based software to capture and compute usage and compliance data. In addition, the Cloud Platform is used for the following:
    - data uploads
    - data storage
    - Firmware over-the-air (OTA)
    - Account access controls
    - event logs (diagnostics)
    - Manufacturer alert notification settings
    - Global/Account dashboard configuration
    - Developer tools

SUMMARY OF NONCLINICAL/BENCH STUDIES

BIOCOMPATIBILITY/MATERIALS

The main component of the Tango Belt is the Smartbelt. The Smartbelt is a patient-contacting device is composed of medical grade PC/ABS (plastics) and biocompatible outer fabric.

The patient contacting components of the Tango Belt include the outer sleeve and belt buckle. These are surface devices contacting intact skin for long term duration (>30 days) based on cumulative use. ISO 10993 Biocompatibility was evaluated in accordance with the FDA Guidance document, "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process,'" issued September 2023, and International Standard ISO 10993-1 "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process,"

ELECTROMAGNETIC CAPABILITY & ELECTROMAGNETIC SAFETY

The Tango Belt was tested for electromagnetic compatibility and electromagnetic safety. Testing was performed to conform to the following FDA recognized standards:

Electromagnetic compatibility (EMC):

- IEC 60601-1-2:2014/A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC/TR 60601-4-2 Edition 1.0 2016-05 Medical electrical equipment - Part 4- 2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- IEC 60601-1-8:2020 Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

Electrical safety:

- ANSI/AAMI ES60601-1:2005/A2:2021 Medical electrical equipment — General requirements for basic safety and essential performance

Wireless Coexistence:

- IEEE/ANSI C63.27-2017 American National Standard for Evaluation of Wireless Coexistence

Battery safety:

- IEC 62133-2:2017 - Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

SOFTWARE AND CYBERSECURITY

The device software documentation was provided according to FDA Guidance document, "Content of Premarket Submissions for Device Software Functions," issued June 2023. The software level of documentation was determined to be Enhanced. Complete verification and validation of all components of the device, including software, hardware, and firmware were provided.

The device cybersecurity documentation was provided according to the FDA Guidance document "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" issued September 2023. The documentation included a cybersecurity risk assessment, threat model, update processes, and labeling. Availability and device recovery was included in the documentation for the Tango Belt Mobile application. Interoperability information was provided as part of the cybersecurity documentation.

HUMAN FACTORS

Human factors validation testing was completed for the Tango Belt per FDA's 2016 Guidance – *Applying Human Factors and Usability Engineering to Medical Devices* and in accordance with *IEC 62366-1:2015_AMD1:2020 – Medical Devices – Part 1: Application of usability engineering to medical devices*. Human factors validation was performed to demonstrate that the user interface for the Tango Belt has been designed such that any use errors that could result in harm or impact treatment have been eliminated or reduced as far as possible.

Three human factor validation tests were conducted to evaluate all three user groups of the Tango Belt. Each human factor validation test included (15) test participants who were representative of the intended users of the Tango Belt for a total of (45) participants (i.e., (15) patients, (15) caregiver-patient dyads, and (15) health care professionals). These HF validation tests included simulated-use testing and knowledge assessments to determine if the Tango Belt and its user interface, including its labeling and packaging, could be used safely and effectively by its intended users, for its intended uses, and in its intended use environments. Results of the HF validation tests demonstrated that Tango Belt can be used by the intended users without serious use errors or problems, for the intended uses and under the expected use conditions.

Tango Belt human factors testing was completed in accordance with the following standards and guidance documents:

- ANSI/AAMI HE75:2009/(R)2018, Human Factors Engineering –Design of Medical Devices
- AAMI/IEC TIR62366-2:2016, Medical Devices Part 2: Guidance on the Application of Usability Engineering to Medical Devices
- ANSI/AAMI/ISO 14971:2019, Medical Devices—Application of risk management to medical devices
- FDA's Guidance Document entitled, "Contents of Human Factors Information in Medical Device Marketing Submissions," issued December 09, 2022
- IEC 60601-1-6:2010+AMD1:2013+AMD:2020, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

DURABILITY

Durability testing was conducted to ensure the Tango Belt can achieve its intended use under anticipated conditions of use:

- Cushion testing conducted to simulate stresses that the Tango Belt cushion assembly may experience during wear. The tests performed were:
    - Finger poke tests of the cushion burst seam to ensure the Tango Belt seam can withstand pins and pokes at the cushion and maintain the seal for the airbag.
    - Twist tests of the entire cushion assembly to ensure the Tango Belt can withstand twists and tangles and maintain the cushion for the airbag.

    - Cycling tests of the entire cushion assembly to ensure the Tango Belt does not deploy from normal wear and tear.
- Drop conditioning testing was conducted to ensure the Tango Belt will not deploy if it is unbuckled, and that the belt will still be functional following an unbuckled fall.
- Drop testing to ensure the belt will sustain a serious fall and the airbag will deploy while worn.

SUMMARY OF CLINICAL INFORMATION

One clinical investigation, *"Mitigation of Major Hip Injury due to fall in an At-Risk, Older Adult Population with a Wearable Smart Belt,"* was performed to evaluate the safety and effectiveness of the Tango Belt. The study was a non-randomized trial performed at eleven (11) investigational sites, all located within the United States. The study enrolled adults aged 65 years and older who have experienced a fall-related fracture after age 50 or who have experienced one or more falls within the past 12 months before enrolling in the study and have a diagnosis of osteoporosis, osteopenia, or prescribed osteoporosis medication, and are able to independently or with caregiver assistance transfer between two surfaces, walk, or move between locations.

The primary objective of the study was to assess the performance of the Tango Belt as an adjunctive to standard of care (SOC) to mitigate fall-related hip dislocation or hip fracture in an at-risk of fall adult population as compared to SOC only. The SOC used in the study is the CDC's STEADI (Stopping Elderly Accidents and Deaths Initiative). STEADI is the standard of care for fall injury risk across settings and has been incorporated into wellness assessments for older adults. The SOC was based on the investigational study and may have differed between sites. In the prospective treatment group, 207 participants were enrolled and 134 completed the study across 10 of the 11 sites. In the retrospective control group, 246 subjects were analyzed across all 11 sites. Participants in the treatment group were instructed to wear the belt every day, and treatment was over a 6-month period. Two control subjects were selected for every 1 subject in the treatment group. Retrospective control subjects were allocated based on a propensity score calculated using sex, age, mobility level, and whether the patient fell in the past year. The performance of the device was determined by the comparison of the proportion of fall-related major hip injuries in the treatment group as compared to the proportion of fall-related major hip injuries in a retrospective control group utilizing only SOC. SOC utilization was verified for each clinical site enrolled. An adaptive trial design was utilized to allow an initial effectiveness target to be evaluated at 6 months.

Following the run-in assessment period, which was a trial period of 14 days to ensure each participant had a minimum of a 64% adherence of wearing the Tango Belt, 134 Tango Belt intervention subjects continued into the in-study phase with 79 intervention subjects reaching the final 180-day assessment visit. The intervention subjects had a 67% overall adherence and an average of 8.8 Tango Belt wear-hours/day.

Results demonstrated that there were no major hip injuries in the intervention group among those wearing the device at the time of a hip-impacting fall, while there were 32 such injuries in the

control group. The one such injury in the intervention group occurred when the device was not in use. Of the subjects who experienced a fall with deployment of the protective airbag, none suffered injuries, and in these incidents, it is assumed that the airbag was protective.

The assessment of adverse events (AEs) revealed no serious AEs related to the Tango Belt. Of the 13 device-related adverse events in the intervention group, there were two categories of discomfort, one associated with use/wear of the device (7) and the other with discomfort that is temporarily experienced from the deployment of the airbag (6). Only one (lower back pain associated with use of the device) was more than mild, leading the participant to discontinue the study. Both types of occurrences were resolved with adjustment or removal of the study device. The six instances of Tango Belt airbag deployment as a result of falls resulted in no serious injuries. However, the attrition rate in the intervention group was high, leading to some uncertainty in the adverse event rate.

Sources of uncertainty overall included the non-randomized nature of the study. In fact, the study group had more frequent falls (0.26 falls per month) than the control group (0.22 falls per month), as well as greater rates of mood and sleep medication use and concerns about falling, indicating group differences that may affect study results. The study was not blinded, potentially resulting in behavioral changes as a result of device use. There was a high rate of attrition in the intervention group, resulting in potential subject selection bias. A retrospective control group was used, and data were often imputed. Additionally, the standard of care for each group was unclear.

Study Results

Effectiveness Assessment

At the end of the study data was compared between the retrospective control group and the Tango Belt group. The study assessed the number of falls of each group to ensure that the groups were comparable, and the number of subjects who experienced a major hip injury due to serious, hip impacting falls.

Group	Falls	Total Subjects with a Major Hip Injury
Control	333	32
Intervention	151	1

The Tango Belt group had a total of 151 falls, and 71 of those falls occurred while the Tango Belt was worn. Sixty-five falls occurred that neither triggered the Tango Belt airbag to deploy nor resulted in major hip injury. Twenty-one airbag deployments were not associated with a fall event or device-related serious adverse event. Six falls that were considered hip-impacting resulted in airbag deployment and did not result in major hip injury. The only major hip injury in the intervention group occurred when the Tango Belt was not worn.

The study demonstrated that the Tango Belt group had a lower rate of major hip injury (1.1%) compared to the retrospective control group (12.1%). This leads to a protective effect of 90.9% when using the Tango Belt with the SOC.

Subject Demographics:

Demographics				
Parameter	***Category***	**Test**	**Control**	**P-Value**
Sex	***Male***	23.9% (32/134)	20.8% (55/264)	0.522
	Female	76.1% (102/134)	79.2% (209/264)	
Age	***Mean***	87.3 ± 7.15 (134)	87.5 ± 6.40 (264)	0.755
	Median	88.0 (82.0, 92.0)	89.0 (84.0, 92.0)	
	Range	(69.0, 106.0)	(68.0, 101.0)	
Race	***American Indian or Alaska Native***	0	0	0.614
	Asian	.7% (1/134)	1.5% (4/264)	
	Black or African American	.7% (1/134)	.4% (1/264)	
	Native Hawaiian or Other Pacific Islander	0	0	
	White	96.3% (129/134)	97.3% (257/264)	
	Other	2.2% (3/134)	.8% (2/264)	
Ethnicity	***Hispanic or Latino***	.7% (1/134)	.8% (2/264)	1.000
	Not Hispanic or Latino	99.3% (133/134)	99.2% (262/264	
Highest Mobility Level	***Independent***	56.0% (75/134)	56.4% (149/264)	0.947
	Supervision	17.9% (24/134)	16.7% (44/264)	
	Limited Assist	25.4% (34/134)	26.5% (70/264)	
	Extensive Assist	0.7% (1/134)	0.4% (1/264)	
	Total Dependence	0.0% (0/134)	0.0% (0/264)	
Fall Risk Factor	***Fell in the Past Year***	93.3% (125/134)	94.3% (249/264)	0.662

Fall Risk Factors			
Parameter	***Category***	**Test**	**Control**
Fell in the past year	***Yes***	93.3% (125/134)	94.3% (249/264)
	No	6.7% (9/134)	5.7% (15/264)
Feels unsteady about standing/walking	***Yes***	21.6% (29/134)	10.6% (28/264)
	No	78.4% (105/134)	89.4% (236/264)
Worries about falling	***Yes***	29.9% (40/134)	8.7% (23/264)
	No	70.1% (94/134)	91.3% (241/264)
Uses Assistive Device (AD) to walk safely	***Yes***	76.1% (102/134)	73.1% (193/264)
	No	23.9% (32/134)	26.9% (71/264)

Unsteady walking	***Yes***	59.0% (79/134)	52.7% (139/264)
	No	41.0% (55/134)	47.3% (125/264)
Poor balance	***Yes***	48.5% (65/134)	46.2% (122/264)
	No	51.5% (69/134)	53.8% (142/264)
Leg weakness	***Yes***	25.4% (34/134)	26.5% (70/264)
	No	74.6% (100/134)	73.5% (194/264)
Urinary urgency/incontinence	***Yes***	34.3% (46/134)	31.1% (82/264)
	No	65.7% (88/134)	68.9% (182/264)
Altered sensation in feet/foot problems	***Yes***	6.0% (8/134)	3.0% (8/264)
	No	94.0% (126/134)	97.0% (256/264)
Medication for sleep or mood	***Yes***	52.2% (70/134)	35.6% (94/264)
	No	47.8% (64/134)	64.4% (170/264)
Orthostatic hypotension	***Yes***	3.7% (5/134)	4.5% (12/264)
	No	96.3% (129/134)	95.5% (252/264)
Depression	***Yes***	41.8% (56/134)	34.8% (92/264)
	No	58.2% (78/134)	65.2% (172/264)
Total Score	***Mean***	4.9 ± 1.94 (134)	4.2 ± 1.82 (264)
	Median	5.0 (4.0, 6.0)	4.0 (3.0, 6.0)
	Range	1.0, 11.0	0.0, 9.0
Brief Interview for Mental Status (BIMS) Score	***Mean***	10.3 ± 5.19 (133)	11.7 ± 3.89 (31)
	Median	13.0 (7.0, 15.0)	13.0 (10.0, 15.0)
	Range	0.0, 15.0	3.0, 15.0
Fall Efficacy Scale (FES-I) Score	***Mean***	15.3 ± 4.29 (63)	
	Median	14.0 (12.0, 18.0)	
	Range	7.0, 26.0	

Adverse Events:

There were 587 total adverse events in the study, 368 in the control group, and 219 in the Tango Belt Group. There were 37 serious adverse events in the tango belt group and 80 in the control group. The adverse events in the Tango Belt group ranged from mild (aware of sign or symptom, but easily tolerated), to moderate (discomfort enough to cause interference with usual activity) to severe (incapacitating with inability to work or do usual activity). Of the adverse events that occurred, 13 were determined to be the result of the Tango Belt, all of which were minor except one which was related to discomfort and increased back pain while wearing the belt and resulted in withdrawal from the study.

No analyses were performed for subgroups.

Pediatric Extrapolation
In this De Novo request, existing clinical data were not leveraged to support the use of the device in a pediatric patient population.

LABELING

The labeling (User Manual) meets the requirements of 21 CFR Part 801.109 for prescription devices.

The labeling includes instructions explaining how to put on, adjust, and clean the device.

The labeling also includes instructions for use for the desktop and mobile Companion Applications of the Tango Belt. The desktop application instructions describe how to manage and monitor multiple Tango Belts as an administrator, as well as how to modify Tango Belt settings for each managed Tango Belt. The mobile application instructions describe how to monitor a single Tango Belt, and how to configure the alerts and displays of the Tango Belt. The mobile application instructions also include a list of all warnings, alerts, and errors displayed and transmitted by the Tango Belt.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of the wearable fall injury prevention device and the measures necessary to mitigate these risks.

Risks to Health	**Mitigation Measures**
Pain or discomfort due to improper fitting of wearable components	Non-clinical performance testing Labeling
Ineffective prevention of injuries during falls	Non-clinical performance testing Software verification, validation, and hazard analysis Electromagnetic compatibility (EMC) testing
Injury from device deployment outside of falls	Non-clinical performance testing Software verification, validation, and hazard analysis Electromagnetic compatibility (EMC) testing Labeling
Adverse tissue reaction	Biocompatibility evaluation
Injury from electrical hazards	Electromagnetic compatibility (EMC) testing Electrical safety testing Battery safety testing

SPECIAL CONTROLS

In combination with the general controls of the FD&C Act, the wearable fall injury prevention device is subject to the following special controls:

(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
    (i) Deployment of protection measures in the case of a fall;
    (ii) Deployment rate when a fall is not occurring; and
    (iii)Device durability.
(2) Software verification, validation, and hazard analysis must be performed.
(3) Performance testing must demonstrate the electromagnetic compatibility (EMC), electrical safety, and battery performance and safety of the device.
(4) The patient-contacting components of the device must be demonstrated to be biocompatible.
(5) Labeling for the user must include:
    (i) Instructions on fitting the device to the user;
    (ii) Information on how the device operates and the typical sensations experienced during use; and
    (iii)Cleaning instructions.

BENEFIT-RISK DETERMINATION

Clinical Benefit

This is a vulnerable population who can benefit from protective devices.

The clinical study results demonstrate that the Tango Belt had a 90.9% protective effect against major hip injury when used in combination with SOC, compared to SOC alone. Those who wore the Tango Belt throughout the study experienced no major hip injuries due to falls. None of the falls that triggered deployment of the airbag resulted in major hip injuries.

The clinical data provided for the Tango Belt demonstrates that the device could detect a fall in progress and reduce the risk of hip dislocation or hip fracture by deploying airbags to protect the user. Data showed that users were less likely to have hip dislocation or hip fracture as a result of falls when using this device.

The proposed device provides three probable benefits when used within geriatric individuals (65+ years of age) who are at risk for hip fracture or hip dislocation due to a fall. First, the proposed device can detect a fall in-progress and discriminate whether the active fall is a serious hip-impacting, non-serious hip-impacting or non-hip impacting. Second, after detection of an in-progress serious hip-impacting fall, the device can deploy an airbag to physically protect the hip region of the belt wearer thereby reducing the risk of a hip fracture or hip dislocation. Third, the proposed device can send an alert to a designated caregiver/healthcare provider(s) signaling for assistance when connected through WiFi.

There is a high level of uncertainty in the Tango Belt's overall protection capabilities:

- Not a randomized study
- Not blinded
- Potential subject selection bias due to attrition rate
- Retrospective control group used
- Unclear standard of care

Risks

Risks were shown to be low, as reported adverse events were minor and infrequent.

A risk associated with the device is the risk of false alarm airbag deployment. The false alarm deployment risk was observed during the study, with 4 occurrences of the airbag deploying without a fall event in a single patient. The false alarm deployments resulted in shock and anxiety from the patient as well as discomfort from the airbag deployment. Deployment of the airbag led to lacerations and bruising.

Some uncertainty in the level of risk exists due to the high attrition rate in the intervention group, perhaps indicating unreported discomfort with the device.

Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

Benefit/Risk Conclusion

In conclusion, given the available information above, for the following indication statement:

> The Tango® Belt is indicated as an adjunctive to standard-of-care to reduce the risk of hip fracture or hip dislocation due to falls in older adults at risk of major hip injury due to falls.
> It is for Prescription Use only.

The probable benefits outweigh the probable risks for the Tango Belt. The device provides benefits, and the risks can be mitigated by the use of general controls and the identified special controls.

CONCLUSION

The De Novo request for the Tango Belt is granted and the device is classified as follows:

> Product Code: SEC
> Device Type: Wearable fall injury prevention device
> Regulation Number: 21 CFR 890.3780
> Class: II