SUMMARY OF: P820003/S117 AND P890003/S265

SYNERGYST II/VERSATRAX PACING REUSABLE SURGICAL CABLES
MEDTRONIC, INC.

EXECUTIVE SUMMARY/BACKGROUND

The purpose of this 180-day PMA supplement is to request approval for design/ manufacturing changes to be made by the contract manufacturer on two surgical cables that are provided to Medtronic (MDT). This file was originally submitted as a 30-day notice on October 22, 2012 but was rejected by the Office of Compliance and converted to a 180-day supplement, because design changes were included. The proposed changes include implementation of a DF-4 lead compatible, crimpable alligator clip onto both the cables, process improvements for the splice yoke of the cables and a change to the wire gauges used in the 2292 cable assembly.

The heat shrink and splice band are the only new materials that are introduced in this process change. Both of these materials will be completely encapsulated within the silicone yoke overmold. Also, the silicone insulation on the alligator clip leads will be the same silicone manufacturer and grade that has been qualified for use on the cable jacket. For these reasons, the firm states that the environmental section of the product specifications, including cleaning, sterilization and biocompatibility, do not require any qualification activity.

DESCRIPTION OF CHANGES/ REASON FOR SUPPLEMENT

The proposed changes include:

1) Incorporation of a DF-4 compatible, solderless alligator clip and associated manufacturing changes onto the 2292 & 5832S reusable cables. The new alligator clip is already in use on a similar Medtronic cable and is designed to accept leads of either IS-l or DF-4 format. The previous alligator clips were designed for IS-l style leads. The lead wire for the 2292 alligator clip will also be modified to a different Silver Plated Copper Wire (same material currently used for the lead wire of the 5832S cables) to allow the use of the same alligator clip and tooling on the 2292 and 5832S cables.

2) Modification of the method in which the yoke (the transition area where there is a split from one cable into multiple lead wires) and cable leads are connected.

(b)(4) Trade Secret

Both materials will be encapsulated within the yoke and will not be exposed. The purpose of this change is to reduce costs needed to create silicone jacketed lead wires and to allow the use of the same alligator clip and tooling across multiple cable models.

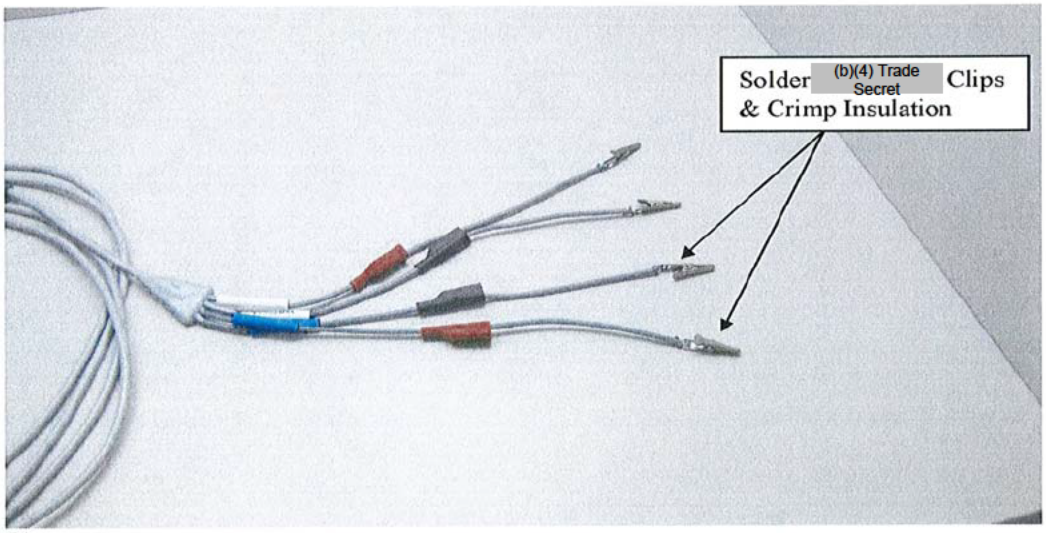
(b)(4) Trade Secret

The purpose of this change is to allow for the use of pre-extruded silicone and crimpable alligator clips.

3) Modification of the bulk cable material for the 2292 cable's Silver Plated Copper Wire. This change is being made in order to improve the tensile strength of the cable. (b)(4) Trade Secret

As such, this change is being implemented to strengthen the cable material. (b)(4) Trade Secret

Figures 1 and 2 show the differences on cable 2292 and further details were provided interactively to elucidate the design change. However, the figures below illustrate that all 4 of the 2292 IS1 clips will be replaced with 4 IS4 clips and the 2 5832S IS1 clips will be replaced with 2 IS4 clips.



5A

Figure 1. Current Solder Alligator Clips and Crimp Isolation on 2292 Cable

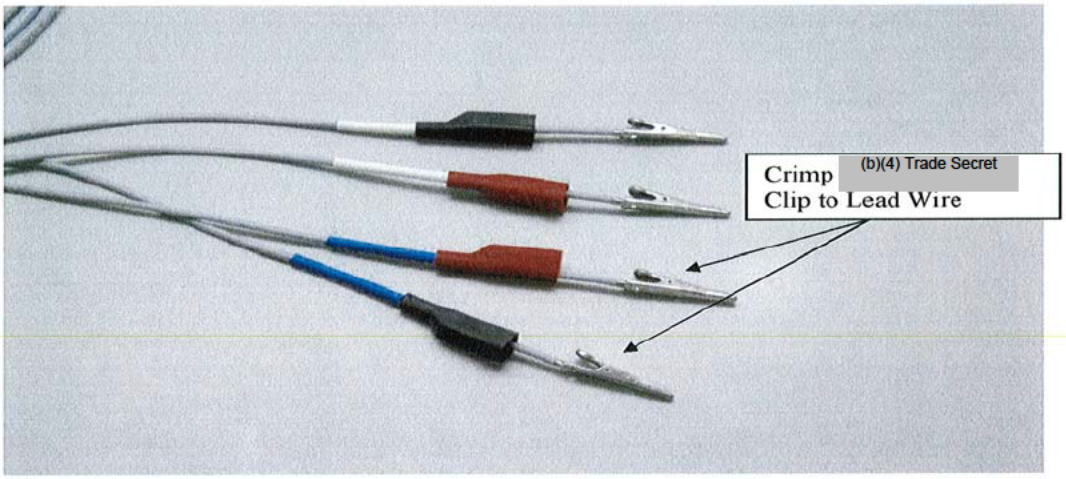


Figure 2. Proposed Solderless Alligator Clips on 2292 Cable

INDICATIONS FOR USE

The intended use of the 2292 cable is: The Model 2292 Analyzer surgical cable is intended to connect the Analyzer, Medtronic Model 8090 or the Analyzer, Medtronic Model 2290 (hereafter, the term "Analyzer" refers to both the Model 8090 and Model 2290 Analyzers) to implantable unipolar or bipolar pacing leads.

The intended use of the 5832S cable is: The 5832 and 5832S Surgical Cables are designed to connect a cardiac pacing lead to a Temporary Pacemaker such as the Medtronic Model 5348. The 5832 Surgical Cable is a cable that does not have exposed pins. The cable's (b)(4) Trade Secret nor can the connector be inadvertently plugged into a power outlet. The cable bifurcates at its distal end and terminates in two alligator clips that attach to the connector pins of the cardiac lead. The 5832S cable has smaller alligator clips compared to the 5832 cable and is better suited to IS-1 leads.

The firm submitted a revised intended use for each cable. A statement is added regarding use of the cable with IS1/DF1 and IS4/DF4 leads. See labeling section below.

DEVICE DESCRIPTION

Model 5832 surgical cable is intended to be used as an extension cable for external pulse generators (EPG). The proximal end is attached to the output terminals of an EPG, while the distal end connects to an indwelling pacing lead. This cable is intended for temporary use during implant of a permanent pacemaker system. Model 2292 surgical cable is intended to be used as an extension cable in conjunction with the Model 2290 analyzer part of the 2090 programmer system. The proximal end plugs into the analyzer and the distal end connects to the implanted patient lead/s. The cable carries electrical impulses between the analyzer and the patient leads.

Figure 3. 2292 Cable- Alligator clips connect to patient leads and proximal end connects to analyzer

REVIEWER NOTE:

While the alligator clip was qualified for use, it was unclear how the firm determined that the specific clips chosen are compatible with DF-4 leads. After speaking with both a mechanical engineer and clinician in the division, it was determined that understanding how the clips are compatible with DF-4 leads specifically, as well as understanding if they are used with an adaptor or clipped directly to the lead are important steps in evaluating the proposed changes. A deficiency was sent interactively to reflect these concerns.

Interactive Deficiency 1

In your submission you indicate that you would like to incorporate DF-4 compatible alligator clips onto the 2292 and 5832S reusable cables. It is unclear how you have determined that the specific clips chosen are compatible with DF-4 leads.

a. Please provide a description of the design elements and/or associated testing on the proposed alligator clips that demonstrate DF-4 compatibility.
b. Please also provide a description of how the clips will be used with the DF-4 leads; in particular, please indicate whether they are intended to be clipped directly to the lead or to an adapter that attaches to the lead connector terminal.
    i. If they are intended to clip directly to the lead, please provide your assessment of the risks of (1) mechanical damage to the lead connector terminals and (2) risk of shorting between terminals when the clips are attached, including a discussion of any mitigations to those risks.

Interactive Deficiency 1 Response and Discussion:

In response to question 1a, the firm states that both design and testing elements support the proposed IS4/DF4 compatibility. A curved section on both the upper and lower jaws allows smooth contact with the ACI. The jaws also include small teeth at the front to enhance connecting to the smaller diameters of lead pins and wires. Compatibility testing for the IS4/DF4 leads was completed and included in this submission. Grip retention on various diameters encompassing the range associated with both IS1/DF1 leads and Medtronic IS4/DF4 ACI products was completed. Clip life cycle, dimensions, and workmanship testing were also completed.

For question 1b, the firm states that the alligator clips are intended to be clipped to an adapter that attaches to the proximal end of an IS4/DF4 lead. An ACI adapter is provided with every Medtronic IS4/DF4 lead and the design includes physical barriers to prevent the alligator clips from touching: each other, multiple conductive rings or the essential insulation between the conductive rings on the lead. The alligator clips are physically prevented from shorting to each other and the lead insulation sections cannot be scratched by the clips.

It appears that the firm has conducted the necessary testing to show compatibility with both IS1/DF1 and IS4/DF4 leads. I spoke with the division's lead expert, who agreed that the grip retention and clip life cycle testing mitigate the risks associated with the clip change. As long as the same ACI adapters are in use with the new clips, there are no increased risks of the clips causing damage or shorting. I have no further concerns with this interactive deficiency.

PRECLINICAL/BENCH

BIOCOMPATIBILITY/MATERIALS

A biocompatibility assessment was provided in the submission, which concluded that the changes described have no effect on biocompatibility. No additional testing is required.

The heat shrink and splice band are the only new materials that are introduced in this process change and both will be completely encapsulated within the silicone yoke overmold. The new clip is made from the same material, processes and supplier as the similar (b)(4) Trade Secret *clip currently used on the 5833 cable. The lead ends will be jacketed by* (b)(4) Trade Secret *using the same materials, processes and supplier as the existing silicone on the larger cable section of the assembly. No new materials or processes will be added. There are no changes to any other external materials. I see no need for additional biocompatibility testing for the currently submitted cables. I have no further concerns.*

BENCH TESTING

The sponsor provided the results of bench testing used to support the changes in the submission attachments. The summary of testing and the results were reviewed and

found appropriate and acceptable. The crimp process for both the crimp and the lead splice were validated in Attachments 3 and 4 of the submission. Qualification of the manufacturing process for the termination of the DF-4 clip was also performed and can be found in Attachments 1 and 2 of the submission. The DF-4 alligator clip has also been qualified for use and is currently used on the Medtronic 5833 cable (FDA cleared October 1992) and is qualified by similarity for use on the 2292 and 5832 cables; the documented equivalency rationale was included. The submission also contains the component level qualification for the DF-4 compatible alligator clips performed by the manufacturer.

The qualifications have proven compliance with existing product specifications. The qualification activities were focused only on the portions of the assembly that were changed, but similarity tests and related results were included for the remaining portions. The crimp process for both the clip and lead splice have been validated. Material, dimensional, spring force, retention, and cyclical test requirements of the clip have been previously qualified. All applicable electrical and mechanical specifications were met with 95/90 confidence.

I spoke with the division's Senior Manufacturing Reviewer regarding the changes in manufacturing processes. He had no additional concerns that were not addressed in the review.

STATISTICAL

A sample size of (b)(4) Trade Secret was chosen to provide 95% confidence that the requirements could be met at least 90% of the time in the qualification testing. The firm states that an Acceptable Quality Level (AQL) 1.0 zero-based acceptance sampling plan was used. A sample of one (1) complete assembly was tested for the operator safety touch current per the IEC60601-1 specification.

The AQL and IEC 60601 are accepted statistical sampling plan standards and the numbers chosen are accurate. I have no concerns with the statistics used.

STERILIZATION AND SHELF LIFE

There was no change in shelf life. A sterilization assessment was provided in Attachment 6, which concluded that the changes described have no effect on the sterilization process and no additional sterilization effectiveness testing is required.

The firm provided a rationale for why the changes described would either improve or have no effect on the cables' sterilizability (the cables are supplied non-sterile and must be sterilized prior to use). The following reasons were cited:

1. *None of the exposed materials used in the cables will be changing. The alligator clips, boots, connectors, yoke and cable jackets will remain the same materials.*
2. *The manufacturing process will require less handling than the current process*
3. *The labeling supplied with the cables includes appropriate instructions for sterilization.*

4. *Changing the* [(b)(4) Trade Secret] *will reduce the chances of foreign material being trapped in the cable ends.*

I agree with the firm's rationale that the changes do not affect sterilizability of the cables and I have no further sterilization concerns.

CLINICAL DATA

There are no clinical issues associated with the submitted changes.

I spoke with a Medical Officer in the division, who confirmed that the changes should not affect the clinical aspect of these products.

PACKAGING

There were no packaging changes.

I asked the firm interactively why the packaging did not change. The firm provided justification and a packaging description with a labeled drawing. [(b)(4) Trade Secret] *The design/manufacturing changes do not impact the packaging. I have no further packaging concerns.*

LABELING

The submission did not include any labeling information, which I requested by email on February 28, 2013. The firm specified that the current user manual for the 2292 cable does not specify the cable for use with IS-1 leads, but the current user manual for the 5832S cable recommends use with IS-1 leads. The Medtronic team decided that updating the labeling is necessary for both manuals to identify the alligator clip lead compatibility. I agree that this is necessary and a deficiency (below) was sent interactively regarding this change.

Interactive Deficiency 2

You have provided a brief description of the proposed labeling for the 2292 and 5832S user manuals with respect to alligator clip lead compatibility. Please provide a clean and redlined version of each user manual with the updated labeling changes.

Interactive Deficiency 2 Response and Discussion

The firm provided the proposed updates for the 2292 and 5832S user manuals along with a table of substantive changes for each. Editorial changes were omitted from the table of changes, but can be seen in the redlined versions. A statement was added to each intended use stating that the cables are intended to be used with Medtronic IS1/DF1 and IS4/DF4 style leads. I ran these changes by a clinician in the division, who did have any further concerns. The clinician noted that the labeling would ideally specify that the cables are intended for use with the ACI adaptors, but that it is enough that the specific lead manuals have the ACI instructions included. Additionally, the current labeling does

not mention the adaptors either. I agree that the additional labeling information resolves the interactive deficiency and I have no further concerns.

RISK ASSESSMENT

The sponsor provided a risk assessment in the submission. The changes did not introduce any new or incremental risks.

The risk assessment listed all the changes and reasoning, as well as testing needed to evaluate the performance and risk of the changes. The manufacturer's Engineering Process Change Report (Attachment 1 of the submission) was referenced to show that the product design and function are not affected by the changes.

End-product level verification testing is summarized in Attachment 2 of the submission and proves compliance with existing product specifications for both models. The changes also necessitate biocompatibility and sterilization testing, but because there is no new exposed material or effect on sterilization process, these tests were not completed (See respective sections above for more information).

The firm also evaluated the necessity for verification testing at the full assembly level and found it unnecessary because all three cables were evaluated at the sub-assembly level, specifically:

- The IS4 alligator clip, (b)(4) Trade Secret *is currently being used on the 5833 cable*

- The (b)(4) Trade Secret *of the crimp to the alligator clip as opposed to* (b)(4) Trade Secret *was tested and evaluated at the sub-assembly level*

(b)(4) Trade Secret

- These cables are 100% electrically tested in assembly for continuity, resistance, shorts, opens and high pot testing.

- There are no new exposed materials on the updated cable.

- The functional performance of the cable has not decreased. The only difference is that the alligator clip used is designed to accept (b)(4) Trade Secret

The firm verified that the failure modes, potential hazards and mitigations identified for the current cables were not impacted. They also confirmed that no new hazard was introduced, that the overall system residual risk was unchanged, and that the change verification and validation activities were satisfactorily completed. I have no remaining concerns regarding the risk analysis.

CONCLUSION

The submission supports a reasonable assurance that the proposed changes for the reusable surgical cables will not impact safety and effectiveness. Additional information was requested interactively regarding the labeling of the cables, the DF-4 compatibility,

and the design change itself. The provided information satisfied any remaining questions after the review of the submission. I support a recommendation of approval.