1. Introduction

EndoformÊ Dermal Template (EDT) is a biologically derived collagen matrix developed for applications in wound healing and tissue regeneration. EDT is produced from ovine forestomachs using a proprietary manufacturing process to decellularize and delaminate the tissue, leaving an intact extracellular matrix (ECM). Post-processing, ovine forestomach matrix (OFM) is freeze-dried and terminally sterilized to give EDT, a shelf-stable, single application device.

The Design Specification for the EDT device defines that the devices may be disposed of without special handling requirements. The purpose of this report is to demonstrate the EDT contains no genetically modified organisms (GMOs), chemicals, or radioactive hazard that would otherwise require special disposal of the EDT devices.

2. Discussion

2.1. Absence of GMOs in EDT

EDT is manufactured from ovine forestomachs according to WI.069. The raw material is sourced from non-GMO sheep. At no stage in the manufacturing process are the materials treated with or exposed to GMOs. Furthermore, the raw materials are not altered in any way that would result in a genetic modification. None of the equipment or chemicals used in the manufacturing process are known to induce a genetic modification (see WI.069.02 and RREDT8.0.051110 and RREDT8.2.00).

2.2. Absence of Chemicals Requiring Special Disposal

EDT is composed predominantly of collagen types I and III (see RREDT2.5.051110) with low concentrations of proteins that naturally occur in association with the extracellular matrix in normal tissues. The EDT device and its constituents have been shown to be safe and biocompatible (see RREDT3.0.051110). The naturally occurring and biodegradable collagens and secondary macromolecules found in EDT do not pose a danger when disposed of in standard waste streams.

EDT is manufactured according to WI.069 using appropriate steps to render the concentration of any potential chemical residue (e.g. detergent residues or ethylene oxide sterilization residues) to levels that are known to be safe (see RREDT8.0.051110, RREDT 8.2.00 and RREDT5.0.051110).

2.3. Absence of Radioactivity

The EDT device is non-radioactive. At no stage in the manufacturing process is the raw material (ovine forestomach) treated either with radioactive materials nor do raw

materials come into contact with radioactive sources. None of the equipment or process chemicals used in the manufacturing process are radioactive.

2.4. Compliance with California Proposition 65

EDT and its associated chemical residues are compliant with California Proposition 65.

3. Concluding Remarks

EDT contains no GMOs, chemicals, or radioactive hazard that would require special disposal and therefore the device may be disposed of using standard waste streams.

4. References

WI.069.02 Endoform Manufacturing Process

RREDT8.0.051110 Process Chemical Testing

RREDT8.2.00 TRIS Quantification

RREDT2.5.051110 Quantification of Collagen I

RREDT3.0.051110 Biocompatibility Testing

RREDT5.0.051110 Ethylene Oxide Residues