

K962425

SEP 11 1996

SECTION VI

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

A. Submitter's Information:

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Date of Preparation: June 11, 1996

B. Device Name:

Trade Name: Bonopty™ Coaxial Bone Biopsy Syswith Eccentric Drill
Common Name: Bone biopsy system
Classification Names: Set, biopsy needle and needle, gastro-urology

C. Predicate Device Names:

Trade Names: Angiomed Osty-Cut Bone Biopsy Needle

D. Device Description:

The Bonopty Coaxial Bone Biopsy System with Eccentric Drill consists of a cannula with a sharp cutting edge and a drill bit (drill) that fits into the cannula. When the biopsy system is assembled, the tip of the drill protrudes beyond the cutting edge of the cannula. The distal tip of the drill has two cutters which do not align with the center line of the drill, as would a conventional drill. During drilling, the eccentric drill tip functions like a guide and forces the drill to wobble in the hole, with the drill tip as a center of rotation. Therefore, the hole created is larger than the outer diameter of the cannula of the needle assembly thus making it easy to advance the cannula over the drill until the cannula is anchored in the bone. Then the drill can be removed and the cannula left in the bone, mounted as a fixed guiding path to facilitate sampling with different biopsy needles or to allow further treatment, without the need to obtain localizing CT scans for each biopsy.

The Bonopty Coaxial Bone Biopsy System with Eccentric Drill consists of a Penetration Set, a Biopsy Set and an optional Extended Drill.

The Penetration Set consists of one Penetration Cannula with stylet (OD 14G, ID 15G, Length 95mm), one Drill (OD 15G, Length 122mm), one Depth Gauge (adjustable length) and one Reference Guide.

The Biopsy Set consists of one Biopsy Cannula with Stylet (OD 15G, ID 18G, Length 160mm), one Ejector Pin, one Depth Gauge (adjustable length) and one Reference Guide.

The Extended Drill (OD 15G, ID 18G, Length 160mm) is optional.

E. Intended Use:

The Bonopty™ Coaxial Bone Biopsy System with Eccentric Drill is indicated for use for biopsy of bone lesions.

F. Technical Characteristics:

The Bonopty™ Coaxial Bone Biopsy System with Eccentric Drill is constructed of biocompatible materials. Most of the materials used in the construction are typical for similar accessories. These include brass and solder.