

**EXHIBIT 7**

**RESPONSE TO SMDA OF 1990**

**SUMMARY OF SAFETY AND EFFECTIVENESS DATA**

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DEVICE NAME: ***PULPDENT Endo-Prep II***

PREDICATE DEVICES: *Ultradent File-Eze*  
*Premier RC Prep*  
*Roth REDTA Chelating Agent*  
*Union Broach Endodilator N-O*

DESCRIPTION AND INTENDED USE: ***PULPDENT Endo-Prep II*** is a 17 % EDTA chelating agent used for debriding and clearing the root canal during endodontic procedures. EDTA aids in the filing process by chelating calcium from dentin. ***PULPDENT Endo-Prep II*** will be offered in two viscosities, thin and thick, so that the dentist can apply the product either directly to the canal opening or to the file.

COMPARISON WITH PREDICATE PRODUCTS: ***PULPDENT Endo-Prep II*** is substantially equivalent in composition and intended use as the predicate products. Please see Exhibit 5 for the entire comparison.

SAFETY AND EFFECTIVENESS: According to *Accepted Dental Therapeutics*, which is a publication of the Council on Dental Therapeutics of the American Dental Association, a buffered, aqueous solution of EDTA (ethylenediaminetetraacetic acid) "...very strongly binds or chelates heavy metal ions, [such as calcium]...[EDTA] may be used as an aid in preparing root canals which resist enlargement by mechanical means."

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## EXHIBIT 5

COMPARISON TABLE OF **PULPDENT ENDO-PREP II**  
AND PREDICATE PRODUCTS

PARAMETER	<b>PULPDENT Endo-Prep II</b>	PREDICATE PRODUCTS	PRE-AMENDMENT OR 510(k)
Chelating agent	Disodium salt of ethylenediaminetetraacetic acid dihydrate (EDTA)	Ultradent <i>File-Eze</i> Premier <i>RC Prep</i> Roth <i>REDTA Chelating Agent</i> Union Broach <i>MoycoEDTA</i> <i>Pulpdent Endo-Prep</i> <i>Pulpdent EDTA Preparations</i>	K934415 Pre-amendment Pre-amendment K950365 K896663 K932791
Buffered water soluble base	Thin and thick formula	Ultradent <i>File-Eze</i> Premier <i>RC Prep</i> Roth <i>REDTA Chelating Agent</i> Union Broach <i>MoycoEDTA</i> <i>Pulpdent Endo-Prep</i> <i>Pulpdent EDTA Preparations</i>	K934415 Pre-amendment Pre-amendment K950365 K896663 K932791
Polyethylene glycol carrier	Thick formula	<i>Pulpdent Endo-Prep</i> <i>Pulpdent EDTA Preparations</i> <i>Ultradent File-Eze</i> <i>Premier RC Prep</i>	K896663 K932791 K934415 Pre-amendment
Intended use	Chelating agent for debriding and clearing the root canal during endodontic procedures. EDTA aids in the filing process by chelating calcium from dentin	Ultradent <i>File-Eze</i> Premier <i>RC Prep</i> Roth <i>REDTA Chelating Agent</i> Union Broach <i>MoycoEDTA</i> <i>Pulpdent Endo-Prep</i> <i>Pulpdent EDTA Preparations</i>	K934415 Pre-amendment Pre-amendment K950365 K896663 K932791