K963766

OCT 31 1996

**3M**

# 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

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Date:                   September 6, 1996
Trade Name:             3M™ ProPlus System
Common Names:           Dental impression material
Classification Name:    Impression material
                        (21 CFR 872.3660)

Predicate devices:      3M™ Imprint™ Vinyl Polysiloxane Impression Material Single
                            Phase System (K882690)

                        Caulk®/Dentsply® Reprosil® Cartridge System (K863287)

                        Kerr® Extrude™ Polyvinylsiloxane Impression Material System
                            (K940379)

                        Examix™ Hydrophilic Vinyl Polysiloxane Impression Material
                            (K880849)


3M™ ProPlus System is composed of three hydrophilic vinyl polysiloxane dental impression materials. The system includes a tray material and two wash materials with different viscosities. The base and catalyst are extruded from two-part cartridges through a mixing tip. The pastes are inserted into the mouth and they cure into a rigid dental impression. 3M™ ProPlus System tray and wash materials are specially formulated to meet the demands of the heavy body/light body impression technique. The tray material may also be used in combination with 3M Imprint™ monophase materials.

3M™ ProPlus System, like the predicate devices, is designed for making precise crown and bridge and denture impressions.

3M™ ProPlus System and the predicate devices have similar technological characteristics as indicated by their vinyl polysiloxane addition cure chemistry. This is further validated by the comparative results of the bench tests conducted. These tests include strain in compression, compression set, mixed consistency, and linear dimensional change.

Based on the safety analysis and the bench tests, 3M™ ProPlus System is safe, effective, and performs as well or better than the predicate devices.